EXHIBIT 4

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

Master File No. 2:12-MD-02327

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL 2327

JOSEPH R. GOODWIN

U.S. DISTRICT JUDGE

Nancy Smallwood, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01662

Alvette Chase v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01533
Margaret Schomer v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01497

Patricia Lindberg, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01637

THE DEPOSITION OF SALIL KHANDWALA, M.D.

JULY 8, 2016

The deposition of SALIL KHANDWALA, M.D.,
Taken at 22731 Newman Street, Suite 200,
Dearborn, Michigan,
Commencing at 9:04 a.m.,
Friday, July 8, 2016,
Before Cheryl McDowell, CSR-2662, RPR.

APPEARANCES:

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KHANDWALA EXHIBIT NO. 8 170

Attachment 4, Gynecare TVT Obturator System

Dearborn, Michigan

Friday, July 8, 2016

About 9:04 a.m.

- - -

SALIL KHANDWALA, M.D.,

having first been duly sworn, was examined and testified on his oath as follows:

EXAMINATION BY MS. FLAHERTY:

Q. Well, good morning, Doctor. My name is Yvonne Flaherty. We met very briefly before we started the deposition this morning. I'm a lawyer from Minneapolis, and I represent plaintiffs in the litigation against Johnson and Johnson and Ethicon, and I have with me today one of the lawyers from my office, Elizabeth Peterson, as well.

We have opened up the telephone lines, but at this point it does not sound like anybody is on the telephone line, and if somebody does join, we'll ask them to identify themselves as well.

It is my understanding that you have been deposed before, and the last deposition at least related to the Ethicon pelvic mesh products was about two weeks ago on June 24th.

Does that sound about correct?

A. That's correct.
Q. Okay. And at that time it was a deposition focused on certain individual or case-specific matters, is that your understanding?
A. That is correct.
Q. Okay. And when I state Ethicon pelvic mesh products, do you understand that to mean products such as the TVT, TVT-O, and TVT-Secur?
A. Yes.
Q. As well as probably some other products that Ethicon has.

Our focus today will be on TVT, TVT-Secur, and TVT-O.

I'm going to hand to you what the court reporter will mark as Exhibit No. 1.

(Khandwala Exhibit No. 1 marked and attached.)

BY MS. FLAHERTY:
Q. Have you seen this document before?
A. Yes, I have.
Q. Okay. And what is your understanding of what this document is?
A. It is basically what we'll be discussing today and going over the information about the cases, the case

specific that we did last time and the general opinions on the three devices that you mentioned.

Q. Okay. And if you turn to page eight of the deposition notice, look at the top of the page, it says Schedule A.

Do you see that?

A. Yes.

Q. And this is a list of items that have been requested from you.

Have you brought any materials with you today?

A. Yes, I have.

Q. Okay. And what do you have?

A. I have the documents and my Reliance List is on this flash drive, my CV is here. The invoices are here. I do not have any photographs.

MR. WALKER: And for the record, we have numerous binders that are outside on a table that are in response to Schedule A that I directed counsel to for inspection if she so desires.

MS. FLAHERTY: And just to clarify, the hard copy documents that are available in binders, it's my understanding that those are hard copies of items that are printed from the Reliance List?

MR. WALKER: Correct.

MS. FLAHERTY: Okay. And not additional items --

MR. WALKER: Correct.

MS. FLAHERTY: -- specific to Schedule A.

MR. WALKER: Correct.

MS. FLAHERTY: Okay.

MR. WALKER: And the hard copies are not all inclusive of his reliance materials. It's just a portion of them that we actually printed. All of them are electronically contained on the flash drive.

BY MS. FLAHERTY:

Q. Okay. So there's just a couple additional items on Schedule A that I want to confirm before we move forward. If you go on to page nine, item number ten talks about consulting agreements, time sheets, billing records, invoices, and it goes on.

I know that you do have an invoice that you brought with you today which I think we will mark as Exhibit No. 2.

(Khandwala Exhibit No. 2 marked and attached.)

BY MS. FLAHERTY:

Q. And the court reporter has handed to you what's been

marked as Exhibit No. 2.

Just so the record is clear, is this a copy of the invoice that you brought with you today?

A. It is.

Q. Do you have other time records or notes or billing records that reflect the time that is set forth on this invoice?

A. Yes, I do.

Q. Okay. And how are those records maintained?

A. Electronically. Whenever I reviewed a document, whether it was a patient-specific or for general reporting, I would just log the start time and the end time, and then I compiled it and created this summary report.

Q. Okay. And I apologize if you said this already. You said it's electronic?

A. Yes.

Q. Is it in an Excel spreadsheet or some other format?

A. It's in just, it's in a Word, Word spreadsheet.

Q. Okay. Do you have any other notes or information on that document other than start and end times of your task?

A. No.

Q. And is that a separate document for each case or is it

a larger document for all of your expert work with respect to the Ethicon litigation?

A. I usually do it per wave. So, for example, this is Wave II, so I just started it, when it started, when I finished a certain task, what that task was, and I just created a little bit of a Word document that will help me eventually compile this particular list.

Q. Okay. Does -- are you able to print a copy of that document?

A. Yes.

Q. Okay. We'll follow up with counsel perhaps during the break to get a copy of that.

And this invoice, Exhibit No. 2, is dated July 5th which is just a few days ago.

Have you put or billed any time since July 5th with respect to the Wave II cases?

A. No, I haven't.

Q. Is there any time that's been billed that's not reflected on the invoice?

A. No, not for Wave II.

MR. WALKER: For Wave II.

MS. FLAHERTY: Correct.

BY MS. FLAHERTY:

Q. And have you started to do work with respect to

Wave III cases?

A. Not yet.

Q. Okay. So you have not billed any time with respect to Wave III cases?

A. That is correct.

Q. Is it fair to say you probably have some ongoing time that you're billing with respect to Wave I cases?

A. Could you please repeat that?

Q. Sure. With respect to -- are you doing any ongoing work with respect to Wave I?

A. Not as of now.

Q. Okay. Do you anticipate any in the future?

A. I may be amending my general report on the vaginal mesh, but that is not certain.

Q. Okay. So going through Exhibit No. 2, the third line down says invoice regarding and that is it states general report.

And that would be your general liability reports for TVT and TVT-O which is one report and TVT-S?

A. That is correct.

Q. And then your case-specific review?

A. Yes.

Q. And that would be for the files of the individual

plaintiffs that you reviewed in Wave II?

A. That's correct.

Q. And then independent medical examinations.

How many independent medical examinations have you conducted in Wave II?

A. Two.

Q. And which plaintiffs were those for?

A. Mrs. Smallwood and Chase.

Q. And then time for the last item on that list is depositions, correct?

A. I'm sorry. Yes.

Q. And that would be your time for the depositions a couple weeks ago, today, and I believe there was one, a third day scheduled for next week.

A. I'm sorry. That does not include -- today is not included in this.

Q. Okay.

A. This is just the last time that I did for the two cases.

Q. Okay. Would it also include your time to prepare for the depositions?

A. No.

Q. Okay. Does it include your time to prepare for the depositions that took place on June 24th?

A. No, just the actual depositions.
Q. Okay. Do you bill separately for your time to prepare for depositions?
A. It's part of the general report or the case-specific review, same, same rates.
Q. Okay. So would the time then be combined with that -- strike that.

Is your time preparing for depositions included in this invoice, at least with respect to the depositions that already happened?
A. Yes.
Q. Okay. And it indicates that you have spent -- I haven't totaled up the number of hours, but you have broken down your hours based on the general report of seventy-two hours, is that correct?
A. That is correct.
Q. And that's for both general reports, total for the general reports?
A. Yes, three.
Q. And just to clarify, when you say three reports, three general reports, which three general reports are you referring to?
A. Two reports of three devices, the TVT, TVT-O being one report and the second is the TVT-Secur.

Q. Okay. I just wanted to make sure we were talking about two reports.
A. Yes.
Q. Three devices but two reports.
Do you know how that time is split out between the TVT-Secur and the TVT, TVT-O report?
A. I'm not sure if it is in my breakup sheet. It could possibly be.
Q. Okay.
A. But I'm not certain.
Q. Okay. Do you have a general recollection?
A. It probably would be about, if I were to guess, it will be sixty percent for the Secur and forty percent for the TVT, TVT-O.
Q. Okay. And case-specific reviews, that looks like it was about ninety-three hours.
And that would be with respect to your preparation in case-specific reports and review of medical records for those reports?
A. Medical records, the depositions, and preparation on the case, write-up of the case and things like that.
Q. Okay. And then it says review with Mr. Walker on June 23rd, five hours.
That I presume was preparation for your

deposition on June 24th?

A. That is correct.

Q. And the IME and report, eight hours.

I presume that is the IME and reports for Miss Smallwood and Miss Chase?

A. That is right.

Q. Okay. And it next says reviews with case-specific attorney and independent pre-deposition review.

What was that?

A. So that is each of these four cases that I did had a case-specific attorney assigned to them. So once I did my report and I reviewed it, I wanted to go back and forth with the attorney to see what were the points of discussion that could come across.

Q. Okay. And so that pre-deposition review would be in addition to any time you spent with Mr. Walker on June 23rd?

A. That is correct.

Q. And then you have the case-specific depositions, five hours on June 24th?

A. That is right.

Q. And so the total for the Wave II work it looks like up through approximately June 24th is ninety-five thousand three hundred dollars?

A. Yes.
Q. Do you know when you plan to prepare your next invoice for Wave II cases?
A. I probably will wait until next week to finish my case-specific reviews, and once those depositions are done, then probably I will do that.
MR. WALKER: I'm sorry. Was your question about Wave II?
MS. FLAHERTY: Yes.
MR. WALKER: I thought your answer was about Wave III.
THE WITNESS: No, Wave II.
MR. WALKER: Okay.
MS. FLAHERTY: There are more case-specific Wave II depositions next week.
MR. WALKER: Thank you. I forgot we have one left.
BY MS. FLAHERTY:
Q. Okay. And are the rates that you have charged and set forth in this invoice similar to the rates charged for your Wave I work?
A. Yes.
Q. Okay. And do you anticipate that these rates will be the same for your Wave III work?

A. Yes.
Q. Do you know how much you have billed thus far with respect to Wave I?
A. I don't recall exactly what my number was, but I'm sure it's somewhere in the file.
Q. Okay. Do you have an estimate?
A. Something thirty-five, forty thousand.
Q. So about a third of what you have billed so far for Wave II?
A. It's possible.
Q. You have also brought with you a thumb drive, is that the correct term, flash drive, thumb drive?
A. Yes.
MS. FLAHERTY: Counsel, is that one that we can mark as an exhibit or --
MR. WALKER: Yes.
MS. FLAHERTY: Okay.
MR. WALKER: It's yours to take, yeah. You can mark it.
MS. FLAHERTY: Okay. We can talk maybe off the record the best way to handle it, but I'm inclined to probably mark it.
MR. WALKER: That's what I've seen done most of the time.

MS. FLAHERTY: So we can probably mark that just so I don't forget as Exhibit No. 3.

(Khandwala Exhibit No. 3 marked and attached.)

BY MS. FLAHERTY:

Q. Going back to Exhibit No. 1 on page nine, number ten also asks about billing records, time sheets, et cetera, with respect to consulting work that you may have done with respect to studies, cadaver labs, personal education training are also listed.

Do you have any documents related to those items?

A. I do not.

Q. Okay. Are you currently doing any consulting work with Ethicon with respect to studies?

A. No, I'm not.

Q. Are you currently doing any work with Ethicon, actually with any manufacturer with respect to pelvic mesh products?

A. Well, I'm about to start.

Q. Okay. What are you about to start?

A. It is a study on vaginal mesh hysteropexy with the Restorelle, R-E-S-T-O-R-E-L-L-E, mesh system, and the company is called Coloplast.

Q. And that's --
A. I'm sorry.
Q. I didn't mean to interrupt you.
A. There's just one more study we are about to start, and that is on tibial nerve stimulation for overactive bladder, and it is with Medtronics.
Q. Let's start first with the study that you anticipate starting soon with respect to Restorelle.

What is your understanding of what your role will be?
A. I am the primary investigator. It is an investigator-initiated study, so it is not a company-sponsored study. So I have initiated the study, and I sent the proposal to the company for sponsorship and their investigative body approved it, and so I will be maintaining the entire control of the clinical trial.
Q. Okay. And how long do you anticipate that clinical trial to take?
A. The enrollment will probably last about nine months and the follow-up is for three years.
Q. And I can't recall. Is Restorelle a product for pelvic organ prolapse or for incontinence?
A. Pelvic organ prolapse.

Q. And with respect to the tibial nerve stimulation study with Medtronic, what do you understand your role to be with that study?

A. I will be one of the coinvestigators. So this is an industry-sponsored trial which Medtronics has started because they're coming up with a new technique for management of overactive bladder, so they want to assess and see how effective it is. So this is the initial clinical pilot trial that we will be involved with.

MR. WALKER: Doctor, let me just say I don't know the terms of any kind of agreements you may have with these other companies, but just make sure you don't divulge anything that's confidential in terms of those agreements when you're answering questions.

BY MS. FLAHERTY:

Q. Are there any other consulting agreements that you have with pelvic mesh manufacturers other than what we just talked about?

A. Well, there are two studies which are closing down. One was the 522 study for Elevate mesh by American Medical Systems or Astora, so they're shutting it down, and the other was with Coloplast on the Exair,

E-X-A-I-R, system which was also a 522 which was shutting down. So it's almost in its final phases of closing down.

Q. And what was your role with respect to the two 522 studies?

A. So as you may know, the FDA had advised that there should be these 522 postmarketing surveys and analysis be performed. So we were part of that in the mesh group to see the role of vaginal mesh for prolapse with the Elevate system and also with the Exair system.

Unfortunately, both these companies decided to shut it down, their products. So we're not doing the study anymore.

Q. Okay. Other than these studies, so we've talked about the upcoming studies on Restorelle and the nerve stimulation study and the two 522 studies that the companies are going to discontinue or shut down was I think how you described it, is there any other consulting work that you are currently doing for pelvic mesh manufacturers?

A. No.

Q. Are you doing any consulting work for Ethicon on products other than pelvic mesh?

A. No, I'm not.
Q. Have you done any?
A. I'm not doing any consulting for pelvic mesh either.
Q. Okay. Have you done any consulting work for Ethicon on any pharmaceutical products?
A. No.
Q. Okay. Are you currently doing any consulting or other work with respect to cadaver labs for pelvic mesh manufacturers?
A. No.
Q. And do you have any plans to do that in the foreseeable future?
A. It's possible.
Q. Okay. Is that with respect to a certain manufacturer or product?
A. It's hard to say. Whatever comes by. So if it is something that is interesting to me, I may do a study, but nothing in the foreseeable future.
Q. Okay. You have done some training and education for Ethicon with respect to pelvic mesh products in the past, is that correct?
A. That is correct.
Q. And have you had agreements or contracts with Ethicon with respect to your role in those training programs?

A. Yes, I have.
Q. Do you have copies of those agreements?
A. You know, those were way back, you know, when the Prolift and Prolift+M meshes were just coming out, so this is we're talking about maybe 2004, 2005. So I'm sure -- I could have them, but it would be hard to dig them out.
Q. Okay. And you've been paid over the years by Ethicon for your assistance in helping with those training sessions, is that correct?
A. That is correct.
Q. Do you have documents that reflect the amount of the monies that you have received from Ethicon over the years?
A. It would probably be on my tax returns, but that's the only way I could find it.
Q. Do you know if Ethicon sends you a 1099 in the years that you do some work for them?
A. Yes, but, again, I don't know how to break it down between a clinical trial because at the same time I was doing an investigator-initiated study on the TVT-Secur in-office, so I was getting reimbursed for that too by Ethicon.

So I don't know how to break up whether I

went for a proctorship course, when I was proctoring at my site, or whether I was being paid for the clinical trial. So they were just giving me a lump sum 1099.

Q. Okay. Do you have records that you submitted to Ethicon when you were working on the TVT-Secur that would reflect the expenses and things that you had?

A. Yes, I'm sure we have that.

Q. Okay. So that's something that you could reproduce?

A. It was in 2006 is when we did the clinical trials, so I don't know if we still have those records. But if it is, we should be able to find it.

Q. Okay. Do you recall, you know, over the years -- well, strike that.

Is it fair to say you've been doing some work with Ethicon for probably the past fifteen to sixteen years?

A. I don't think I have been doing for since maybe 2008, 2009.

Q. Okay.

A. I haven't done much. I have done my own clinical trials using the Ethicon products but not for Ethicon.

Q. Okay.

A. So I believe it may have spiked around the time when

the TVT-O, the TVT-Secur, and the Prolift+M meshes were just getting started.

Q. Okay.

A. So maybe about six years or so, around 2002 to 2008 possibly.

Q. Okay. So you think that was probably the peak of your work for Ethicon?

A. Yes.

Q. Okay. Do you know during that roughly four- to five-year time period about how much money Ethicon paid you?

A. No, I'm sorry, I don't.

Q. And that would be something that you think would be on your tax returns or the 1099s?

A. Yes. However, it will again be mixed with my clinical trial, so I do not know how to differentiate that.

MR. WALKER: And I just want to put on the record, I believe we have an outstanding objection to the request for Doctor Khandwala's 1099s.

BY MS. FLAHERTY:

Q. On the -- you had mentioned that it's difficult to discern which monies might be associated with training or consulting and which might be associated with clinical trials, is that fair?

A. That's correct.
Q. I want to make sure I have an understanding of the money that comes with respect to the clinical studies. Can you describe that for me a little bit?
A. Yes. So the TVT-Secur study that we did was an investigator-initiated study. That means I initiated the study, and I sent the proposal over to the Ethicon research committee and they approved it.

Once they approved it, then we had set some specific budget, timely budget, and they paid for those invoices, for example, when it went for the IRB, when the initial patients enrolled, when we got the consents, when they came back for their surgery, when they came back for the postoperative visits. So for all those activities performed, invoices were made and submitted to Ethicon once they're created.
Q. Do you have any recollection of what those invoices totaled for the TVT-Secur study?
A. I'm sorry, I don't know offhand.
Q. Do you know if it was above one hundred thousand?
A. Very unlikely.
Q. Okay. If we go on Exhibit No. 1 down to number twelve, it asks for correspondence and other communications with employees of defendants with

respect to the female pelvic mesh products.

Do you have a file or a correspondence folder for your communications with the company?

A. No, I do not.

Q. Okay. Is there anyplace where you keep e-mail communications that you may have with Ethicon?

And just to clarify, I'm not talking about any communications that you may have with lawyers that are representing Ethicon. These would be communications directly with Ethicon.

A. No, I do not keep any folders or any e-mails.

Q. Okay. Do you have a file with respect to the TVT-Secur study that you did with Ethicon?

A. For the study itself?

Q. Yes.

A. Yes, I do.

Q. Okay. And would that study -- or strike that.

Would that file include communications that you may have had with Ethicon during that time period?

A. So, again, the study was an investigator-initiated study, so Ethicon did not have any role to play in this study. So all the information in the study would be pertaining to the study documents, you know, and the study paper that was done and eventually

published, and there were no communications with Ethicon. I was not obliged to inform them as to what was going on.

And that's one of the main things that we had set up is that Ethicon will not influence or impact the clinical studies or the clinical outcomes, it will be entirely up to us to do it. So the only interaction and e-mails that could have gone back and forth would be sending them invoices for that particular setup for that period of time.

Q. And is it fair to say there would have been some initial communication when you approached them with respect to the study that you were doing?

A. That is correct.

Q. And with respect to some of the training and I'll call it nonclinical study work that you have done with Ethicon, how do they communicate with you about those sessions?

A. Well, it depends on what was the session. If it was a proctorship at my site where surgeons were coming in, then it would be the local representative for Ethicon who would set it up and let me know that a few doctors are coming in on a certain date, was it okay with me, and then we would arrange it with the hospital. So

that's how it would happen.

If I was to go to a site to do a cadaver lab, then it would be set up by the manager of the area or the educational person in charge for Ethicon. They would set it up and they would call me and ask me whether I would want to be a proctor for that particular course, cadaver course.

If it was training at a doctor's site where I had to visit a doctor to go, then a particular manager of that district, you know, sales manager or someone, would call me and say could you come and proctor this doctor on this particular product.

So it all depends on what was the outcome, what was being asked.

Q. Okay. And if those communications were via e-mail, it sounds like you probably would not have saved those e-mails?

A. Most of the communications I believe were verbal, a phone call, a rep letting me know in the operating room that this is happening.

Q. Okay. And how -- actually, strike that.

A. And I think most of these happened around 2004. I highly doubt if I did any consulting of significance after 2007.

Q. Okay. Do you recall when the last time was that you had communication with an Ethicon employee? Again, not the lawyers, just the Ethicon employees.

A. When I had gone for a court case in Texas, I believe it was last year, Butler Snow, and I think I met Mr. -- well, he was not employed, Mr. Hinoul. I don't think he was employed. So it's been a long time since I've communicated with any existing employees.

Q. Okay. And we'll get into this a little bit further later, but since you mentioned 522 studies, I want to ask so I don't forget.

Was the TVT-Secur -- strike that.

The FDA had indicated that J & J also needed to do a 522 study on the TVT-Secur, is that correct?

A. That is correct.

Q. Did you do any work with respect to -- well, first of all, did they start the 522 studies on the TVT-Secur?

A. Not that I'm aware of.

Q. Okay. Did you do any consulting with Ethicon with respect to the 522, potential 522 studies on TVT-Secur?

A. No.

Q. Okay. You had mentioned that you've done various

types of training, primarily several years ago, with respect to Ethicon's pelvic mesh products.

Did you ever speak at what I would call a symposium or a conference perhaps to other medical professionals?

A. Yes, I did.

Q. Okay. Did you have any presentation materials related to those speeches or presentations?

A. Yes.

Q. Okay. Do you maintain copies of those materials?

A. Not specifically for a conference as such but just overall slides that I do have.

Q. Okay. And are those something that you maintain?

Well, how do you maintain those?

A. In a PowerPoint presentation, so it's usually by topic. If I'm talking on stress incontinence, it will be a stress incontinence slide set, and if it is prolapse, it will be on a prolapse slide set. So it will be by subject.

Q. And is that something you maintain electronically?

A. Yes.

Q. And so you would have copies of those on your computer system?

A. Yes.

Q. Okay. In addition to the PowerPoints, would you have any other course materials that you would maintain?
A. Are you asking specifically for something or just overall?
Q. Just with respect to Ethicon pelvic mesh products.
A. So this could be for, if I understand correctly, this could be for training anybody, it could be any residents, anybody?
Q. Yes, correct.
A. Yes. Well, we do have in an electronic format that we have in our patient medical records because we do go over that information with our patients when they come in to the office for incontinence and we are talking to them about different techniques of management of incontinence.

So we explain to them about what a TVT is, what a transobturator sling is, what a mini sling is. So that information is there, and then electronic medical records, the risks, benefits, what it is and things like that.
Q. Okay. And I think I probably didn't phrase the question very well. What I'm wondering about is when you would give a presentation at a symposium or to another group of medical professionals regarding

pelvic mesh products, would you prepare course materials?

A. Not usually. It's more of, more often than not it's a slide set. If I'm giving out anything, it's usually my published papers.

Q. Okay. Do you have any videotapes or other electronic or digital I guess depictions of your presentations?

A. I don't.

Q. Okay. Do you know if other people have those?

A. I do not know.

Q. Did you ever participate in any market evaluations with respect to Ethicon's pelvic mesh products?

A. Could you please explain?

Q. Sure. On Exhibit 1, the bottom at page nine, it also asks for marketing evaluations created or provided, created by or provided to you.

A. Yes. I believe there was a time when -- I do not know if it was marketing or education to the news media. There's one time when I was interviewed by the news media about the Prolift or the Prolift+M system. I do not recall which one it was. This was several years ago, and I think it came in some newspaper that Doctor Khandwala was interviewed and this is what he said.

Q. Okay. Did you -- with respect to the TVT-Secur study, did you maintain minutes for any study meetings that may have occurred?

A. Well, there were three different studies.

MS. FLAHERTY: Off the record.

(Off the record at 9:39 a.m.)

(Back on the record at 9:39 a.m.)

THE WITNESS: So there were different clinical trials, so one was as I mentioned the investigator-initiated study. I do not have any minutes on that.

Then there were two others, but I do not know if Ethicon would have kept the minutes. One was the TVT World Registry which Doctor Tincello, T-I-N-C-E-L-L-O, he was the person in charge. So I'm not sure if they kept the minutes.

And the other was the initial pilot clinical trial that we did with the TVT-Secur in 2006, and that, I did not keep any minutes. I don't know if anybody else did.

BY MS. FLAHERTY:

Q. Do you have -- with respect to the initial clinical trial and the investigator-initiated trials for Secur, do you have what I'll call raw study data that you

have maintained?

A. For the investigator-initiated trial? Yes.

Q. Okay.

A. I think I'm obliged to keep them for a certain number of years, but I still kept the case-specific reports.

Q. Okay. And how are those maintained?

A. In hard copy.

Q. Are those hard copies maintained here at your office or in another location?

A. In a storage, it has to be in a storage facility.

Q. Where is that storage facility located?

A. It's somewhere in Dearborn, close by.

Q. Have you testified before the FDA or any other governmental agencies with respect to pelvic mesh products?

A. I have not.

Q. Okay. Do you have any graphs or presentations or charts that you may have used during the trial in Texas?

And I'll just clarify that. That were actually used in front of a jury. I'm not talking about things you discussed with your lawyers during the trial.

A. No, I don't.

Q. Okay. So we talked about the invoice, the hard copy binders, and the thumb drive that you have brought with you today.

Are there any other materials or items that you have brought in response to the deposition notice that we have not yet discussed?

A. The outside information also included, the hard copy.

Q. Correct. The binders?

A. Yes.

Q. The binders of hard copies?

A. Yes.

Q. Is that the totality of everything you have with you for today?

A. Yes.

Q. Okay.

MR. WALKER: In addition to his report and cited material in those reports.

MS. FLAHERTY: Understood.

MR. WALKER: Yeah.

MS. FLAHERTY: Why don't we mark the two reports as exhibits.

MR. WALKER: Can we go off the record?

MS. FLAHERTY: Yeah, let's go off the record.

(Off the record at 9:42 a.m.)

(Back on the record at 9:43 a.m.)

(Khandwala Exhibits Nos. 4 and 5 marked and attached.)

BY MS. FLAHERTY:

Q. Okay. So the court reporter has handed you what has been marked as Exhibit No. 4 and Exhibit No. 5.

Do you have those in front of you?

A. Yes, I do.

Q. Okay. And let's start with Exhibit No. 4.

Do you recognize this document?

A. Yes, I do.

Q. Okay. And what is it?

A. It is my general report on TVT and the TVT-O system.

Q. Okay. And is that your signature on the first page?

A. Yes, it is.

Q. Okay. And that's dated June 3rd, 2016, correct?

A. Yes.

Q. All right. And since you issued this report just a little over a month ago, have you made any changes to the report?

A. No, I have not.

Q. Do you currently have any plans to amend this report?

A. Currently, no.

Q. Okay. Do you anticipate that you may be seeking to amend it in the future?
A. It is possible.
Q. Do you know when you may make that decision?
A. For example, if I get some new information on new studies that might come up and I have to add them into that, if it is pertinent enough, then I may do it.
Q. Okay. But as you sit here today, are there any studies or other information that you feel needs to be added to Exhibit No. 4?
A. No.
Q. Okay. And the other document that is in front of you is Exhibit No. 5?
A. Yes.
Q. And do you recognize that document?
A. Yes, I do.
Q. And what is that?
A. It is my report on the TVT-Secur suburethral sling system.
Q. And on page one, is that your signature?
A. Yes, it is.
Q. Okay. And this report is also dated June 3rd, 2016, is that correct?
A. That is correct.

Q. Okay. And have you made any changes to this report?
A. I have not.
Q. So she doesn't get mad at us. I know you can anticipate, but, and as you sit here today, do you have any plans to amend Exhibit No. 5?
A. No, I do not.
MS. FLAHERTY: Okay. Why don't we mark the CV.
(Khandwala Exhibit No. 6 marked and attached.)
BY MS. FLAHERTY:
Q. The court reporter has handed you what has been marked Exhibit No. 6.
Do you recognize this document?
A. Yes, I do.
Q. And what is this?
A. It is my curriculum vitae.
Q. Okay. And I'll represent to you that we obtained this exhibit, it was attached as the CV to your reports.
Have you made any changes to your CV since June 3rd of 2016?
A. No, I have not.
Q. Okay. And as you sit here today, are you aware of any -- anything that needs to be changed on your CV?

A. No.
Q. Okay. Do you have any presentations or publications that perhaps are pending that are not yet listed on your CV?
A. Yes.
Q. Okay. And what are those?
A. There are two clinical trials that we have just submitted for publication.
Q. What are those clinical trials?
A. One is on the Exair, that's E-X-A-I-R, mesh system for vaginal mesh hysteropexy, and the other is the MiniArc suburethral sling procedure for stress incontinence.
Q. And the MiniArc, that is an American Medical Systems product?
A. That is correct.
Q. I think they actually have another name now.
A. Astora.
Q. Correct.
And the other one, Exair, is that Coloplast?
A. Yes.
Q. Okay. Do you know or anticipate when those studies will be published?
A. We haven't heard back from the reviewers yet. We've

just sent the documents over.

Q. And how long does that process usually take?

A. It could take up to about four weeks for them to review it, and then if they come with edits, then we have to go back and forth with the edits. So it could take up to a couple of months.

Q. Do you have -- let's start first with the MiniArc study. Do you have a coauthor or cosponsor -- I'm not quite sure what the correct phrase is -- on that study?

A. It is our own study. It is a non-sponsored study and there is no coinvestigator.

Q. And when you say our own, you mean Doctor Khandwala and his office?

A. That is correct.

Q. Okay. And with respect to the Coloplast product, Exair I think it is called, do you have any coauthors or coinvestigators with you on that?

A. No. However, that is an investigator-initiated study, so it was sponsored by Coloplast, but Coloplast had nothing to do with the study design or the writing of the paper or enrollment.

Q. Has Coloplast seen a draft of the paper?

A. They have not.

Q. All right. Are those the only two studies or papers that are currently pending that are not listed on your CV?

A. That is correct.

Q. Okay. And then on the very last page of your CV, under references, it looks like those are redacted. I'm assuming that's the names of other doctors or colleagues of yours?

A. Yes.

Q. Okay. And one other thing I wanted to ask. With respect to the last page, it lists your professional memberships.

A. Yes.

Q. The American College of Obstetrics and Gynecology, that's also known as ACOG?

A. Yes.

Q. Yes.

A. Yes.

Q. And the American Urogynecology Society?

A. Yes.

Q. Are there any others that you participate in as a member?

A. No.

Q. You can set this exhibit aside.

(Khandwala Exhibit No. 7 marked and attached.)

BY MS. FLAHERTY:

Q. All right. The court reporter has handed you what has been marked as Exhibit No. 7.

Do you recognize this document?

A. Yes, I do.

Q. And what is this?

A. It is my Reliance List.

Q. And we had previously conferred with counsel for Ethicon, and it's our understanding that the Reliance List for both your TVT-Secur and your TVT, TVT-O reports are identical.

Is that your understanding?

A. It's all together.

Q. So it's one comprehensive list?

A. Yes.

Q. Okay. It's a long list, so we didn't want to compare line by line if we didn't have to.

And since you prepared the report on June 3rd, are there any materials that you feel need to be added to this Reliance List?

A. No.

Q. Okay. Aside from your own personal experiences, I

know you've been practicing for many years, Doctor, does the Reliance List contain the totality of information that you relied upon with respect to your opinions in your reports?

A. Besides my experience, yes.

Q. Okay. And have you reviewed all the items that are on the Reliance List?

A. Yes, I have.

Q. You personally or have some people assisted you?

A. No, I reviewed it myself.

MR. WALKER: I'm sorry. Assist in the compilation or the review?

MS. FLAHERTY: The review of the materials, not preparation of the list.

MR. WALKER: Okay. Object to form.

MS. FLAHERTY: Okay. That's fine.

BY MS. FLAHERTY:

Q. Do you know when you last reviewed items that are listed on the Reliance List?

A. Just about a couple of days ago when I was again reviewing for the general report.

Q. And I can't recall but I think you had on your invoice roughly how much time you have spent in preparation of the report.

Does that time -- thank you. Does that time include reviewing the materials that are on the Reliance List?

A. Yes.

Q. Okay. So the seventy-two hours listed for the general report and then there are some additional hours for the case-specific reports.

A. However, several of these papers I have already reviewed before, so I've been ongoing reviewing these articles because we publish all the time. So when you're publishing, you have to know several of these topics.

So, in fact, when I was publishing for the Exair paper, in the discussion you have to know what other prolapse studies were done. So I keep reviewing these and I keep reviewing these articles on an ongoing basis.

So several of these articles and papers I'd already reviewed, and that's why I put it in my Reliance List, and some I reviewed as preparation to the general report.

Q. Okay. Do you recall when you first started to receive materials to review with respect to your report? And I will -- I understand some of the studies you've read

over the years. But with respect to the other materials, do you recall when you first started to review those?

A. When I started compiling the general report and I was wanting to see what other articles were there, so I usually contact my hospital library and I give it a list of articles that I would want to see.

So, for example, if I read a paper and I find that in the reference of that paper there are some interesting articles, I would highlight them and my secretary would send the list over to my librarian, and my librarian would pull it up and send it back to me electronically. So that's how most of those articles are compiled, especially the medical literature articles were compiled in that fashion.

The Ethicon documents, however, I had some of the documents I had from the previous trial, and then when I looked at plaintiffs' depositions, especially plaintiffs' expert depositions, and when I read them and some of these documents were referenced, I contacted the attorneys to see if they could help track some of those documents for me.

Q. Okay. Did you also receive perhaps a DVD or some other storage -- strike that -- DVD or some other

method of transmitting Ethicon documents that perhaps Ethicon provided directly to you?

A. I think most of it was electronically.

Q. Okay.

A. E-mail.

Q. And some of those you asked for and some of those Ethicon provided because they thought they would be relevant to your review?

A. That is correct.

Q. Okay. You had mentioned that you go to a librarian at the hospital?

A. Yes.

Q. Which hospital is that?

A. It's called Beaumont, Beaumont Dearborn Hospital. The name has just changed.

Q. Is that here in Dearborn, Michigan?

A. Yes.

Q. Is that the hospital where you have privileges?

A. Yes.

Q. Would that be considered your primary hospital?

A. Yes.

Q. Okay. Is that where you conduct your surgeries?

A. It is another hospital but in the same system.

Q. Okay. Are there other hospitals in Michigan or

elsewhere where you have privileges?
A. It is under the same umbrella called Beaumont Health System.
Q. Okay.
A. But two different hospitals, one is in Dearborn, one is in Annapolis.
Q. Okay. Annapolis in Michigan or Annapolis in a different state?
A. Michigan.
Q. Are there any documents that you had asked for that perhaps Ethicon wasn't able to locate or has not yet been able to provide?
A. I don't recall.
Q. Okay. I believe your Reliance List materials indicate that you had reviewed some of the deposition transcripts for plaintiffs and perhaps some doctors, is that correct?
A. That is correct.
Q. Have you reviewed deposition transcripts for any of plaintiffs' expert witnesses?
A. Yes, I have.
Q. Have you reviewed any videotapes of any depositions?
A. No, I have not.
Q. So your review of depositions would have been done via

reading a transcript?

A. That is correct.

Q. Okay. As you prepared your reports, I believe they are marked as 4 and 5, did you consult with any other experts as you prepared those reports?

A. No, I did not.

Q. Other than your lawyers, did you consult with anyone else while you were preparing the two reports?

A. Actually, I did not even consult with my lawyers about the report. I did the report entirely on my own.

Q. Okay. Do you have any staff or assistants that help you with perhaps assembling some of the materials and things?

A. Yes, just as I mentioned, mainly to get the articles from the librarian. My secretary would go and get those articles, and I give her a highlighted list of which articles I need, and then once she brings it, I will highlight the text and she would type that text and, you know, compile it for me, and I would review that and put it in my report.

Q. Okay. Do you keep any time records for your secretary or any other staff that may be assisting you?

A. Actually, I do not.

Q. Okay.

A. Maybe I should.
Q. Sorry.
We had talked a little bit earlier about some of your consulting work with Ethicon and some other companies.
Are there any other companies that you have consulted for in the past with respect to medical devices?
A. Yes, I have.
Q. Okay. And what are those companies?
A. Coloplast, American Medical Systems, slash, Astora, Medical Devices, Medtronics.
Q. Okay. And the Medtronic consulting, is that with respect to the I think it was a stimulation device for incontinence?
A. Yes, but I'm not doing it that much for the InterStim. It's more for the tibial nerve stimulation which is an upcoming study.
Q. Have you done any consulting on the InterStim?
A. No, I have not.
Q. Okay. Do you still treat patients, Doctor?
A. Yes, I do.
Q. On an average week, about what percentage of your workweek is devoted to treating patients?

A. About seventy percent.
Q. Is the other thirty percent related to litigation activities?
A. No. It is mainly related to clinical trials, my ongoing studies, education, because I teach at least two OB/GYN residents per month on an ongoing basis.

And we did have a fellowship until now but my fellow had to leave, but we're expecting a fellow within a few weeks. So it's training the fellow and then some of the typical administrative activities that you have to do to run an office.

Q. You had mentioned that you teach two OB/GYN residents per month.

When you say typically, is that a formal program that you do at one of the colleges or medical schools, or is it more of an internship with your, with your practice?
A. Each OB/GYN program has a requirement where the residents have to do some type of subspecialty rotation, and one of the subspecialty rotations that they're expected to do is in urogynecology.

So there are four programs which have OB/GYN residencies, and they send their residents to me. One is the Wayne State University School of

Medicine, so I am their main urogynecology faculty. Then the Oakwood, slash, Beaumont Dearborn Hospital Medical System. Third is Botsford Hospital and fourth is Genesys Hospital.

So these are four hospitals in my area where they have OB/GYN residencies, and their residents come to me for their urogynecology training.

Q. Okay. And how long does that training typically last?

A. It's typically between one to two months.

Q. Okay. And is that -- is it fair to say that that training is not necessarily specific just to pelvic mesh products but to the larger urogyn practice?

A. Yes, correct.

Q. Would that also be similar with respect to your training of fellows?

A. Yes.

Q. Okay. Have you ever served as an expert for a pelvic mesh company other than Ethicon?

A. No.

MR. WALKER: In litigation?

MS. FLAHERTY: In litigation, yes.

THE WITNESS: No.

BY MS. FLAHERTY:

Q. Okay. Have you ever served as a litigation expert for

any type of case other than the current Ethicon pelvic mesh cases that you're working on?

A. Yes, I have.

Q. Okay. Did any of those involve medical devices?

A. Yes.

Q. Did any of those involve pelvic mesh products?

A. Yes.

Q. Can you describe those for me, please?

A. It was an Elevate system which is an American Medical System product, and it was a case against one of the doctors who had implanted that device. So I was involved as an expert. I was deposed as an expert.

Q. And for whom were you an expert?

A. For the doctors, the defense attorney.

Q. So in that Elevate case, the plaintiff's lawyers had alleged that the doctor may have done something wrong, is that correct?

A. That is correct.

Q. And you were retained to testify as to whether or not that doctor did anything wrong?

A. Yes.

Q. Okay. And was it your opinion that the doctor did not breach any standard of care?

A. Yes.

Q. Okay. Did that case go to trial?
A. No, it did not.
Q. Okay. But you were deposed?
A. Yes.
Q. Did you issue a report on that case?
A. Yes, I did.
Q. Do you recall where that case was located?
A. Where I was deposed?
Q. Not physically where your deposition was but where the case itself was pending.
A. I think it was Arkansas.
Q. Have you ever served as an expert, litigation expert, in other medical malpractice cases?
A. Not that I recall.
Q. Okay. Have you ever served as an expert, have you ever served as a litigation expert on behalf of a plaintiff in any type of litigation?
MR. WALKER: I'm going to object to form.
THE WITNESS: Not that I recall.
BY MS. FLAHERTY:
Q. Are there any other cases in which you have served as a litigation expert, again, other than Ethicon and the Elevate case that you just mentioned?
MR. WALKER: Object to form.

THE WITNESS: Not that I recall.

BY MS. FLAHERTY:

Q. Okay. You had indicated that you still treat patients, and that's about seventy percent of your time at this point, your work, your work time?

A. That is correct.

Q. Do you -- on average, about how many patients do you see per week?

A. About anywhere from seventy to eighty patients.

Q. Do you have a general breakdown of how those patients -- how many of those patients come to you with urinary stress incontinence issues?

A. Let's see. Well, all of those are not new patients. But if you just take all of them, if it's new consultation or established patients, I would probably say maybe about twenty, twenty-five percent.

Q. This may seem like a silly question but I'll ask. Do you treat any men for uro issues?

A. No.

Q. Okay. So your practice is one hundred percent female based?

A. Yes.

Q. Okay. And approximately what percentage of your patients do you treat for pelvic organ prolapse?

A. Similar percentage, about twenty-five percent.
Q. And so the other fifty percent of your patients is it fair to say see you for a variety of gynecological or urogynecological issues?
A. My practice is essentially entirely urogynecology. So they may be coming for overactive bladder, urgency incontinence, pelvic pain, painful bladder syndrome or urgency and frequency, mixed incontinence. So that's predominantly what I would be seeing otherwise.
Q. Okay.
A. Bladder infections.
Q. You had mentioned that you testified at a trial down in Texas?

MR. WALKER: Object to form.

BY MS. FLAHERTY:
Q. Have you testified at trial before?
A. No.
Q. Okay. So you've never testified at any trial, pelvic mesh or otherwise?
A. No.
Q. Okay. Do you want to take a break? It's about an hour.
A. I'm fine.
Q. Okay. I know some people like a break every hour or

so.

Have you conducted any -- strike that.

Have you ever worked for the FDA?

A. No, I have not.

Q. Have you ever done any consulting work for the FDA?

A. No, I have not.

Q. Have you ever served as a regulatory consultant?

A. No, I have not.

Q. Have you done any work commenting or helping to draft proposed regulations with the FDA?

A. No, I have not.

Q. Have you done any work advising or consulting on compliance issues with the FDA?

A. No, I have not.

Q. Okay. Do you consider yourself an expert with respect to FDA regulations?

A. No, I do not.

Q. Have you ever done any work drafting warning labels for any kind of medical product?

A. No, I have not.

Q. Okay. And so that would include no warning labels with respect to pelvic mesh products?

A. That is correct.

Q. Okay. Have you -- strike that.

Do you have -- you're not a pathologist, are you?

A. I am not.

Q. Okay. And so you don't have any certifications with respect to pathology?

A. I can see slides. As a part of gynecology residency, we do a pathology rotation. So we can see slides and understand how to read slides, but I'm not a certified pathologist.

Q. Okay. And you have not previously served as an expert specific to issues on pathology?

A. That is correct.

Q. Okay. And you are not a toxicologist, are you, Doctor?

A. I am not.

Q. Okay. And you have not previously served as an expert on issues specific to toxicology?

A. That is correct.

Q. Are you familiar with the term Device History File?

A. No, I'm not.

Q. Okay. Is it fair to say then that you have not worked on a Device History File?

A. That's correct.

Q. Okay. Are you familiar with the term DFMEA?

A. No, I'm not.
Q. Okay. How about Design Failure Mode Effects Analysis?
A. No, I'm not familiar.
Q. Okay. So, again, fair to say that you probably have not worked on Design Failure Effects Analysis?
A. That is correct.
Q. Okay. Similarly, are you familiar with the phrase FMEA which is Failure Mode and Effects Analysis?
A. No, I have not.
Q. Okay. And you have not done any work specific to Failure Mode and Effects Analysis?
A. That is correct.
Q. Okay. And one more for you. I know they sound similar. FMMEA which is Process Failure Mode Effects Analysis.

Are you familiar with that?

A. I am not.
Q. Okay. And so you have not done any work specific to Process Failure Mode Effects Analysis?
A. That is correct.
Q. I forgot to ask this earlier. Have you ever been on an FDA advisory board?
A. No, I have not.
Q. Have you ever communicated directly with the FDA

regarding your opinions on pelvic mesh products?

A. Yes, I have.

Q. Okay. And in what context was that?

A. It was a paper that we had submitted with the lead author being Miles Murphy in response to the FDA advisory of 2011.

Q. Do you know if that paper was published?

A. Yes, it was.

Q. I'm sure it's on your list, but do you recall where, in what journal or where it was published?

A. I think it was the American Urogynecology Journal, the Gold Journal.

Q. Are you familiar with the phrase MAUDE Report?

A. Yes.

Q. Have you ever filed a MAUDE Report?

A. I have not.

Q. Do you differentiate between a MAUDE Report and an Adverse Event Report?

A. It depends on if it's part of a clinical trial because many of my patients are part of clinical trials. So if it's part of a clinical trial, then we have to do a case-specific form called a CRF, and that has to be filed with the Institution Review Board.

If there's any adverse event, whether it is

a serious adverse event or just an adverse event, so that would be to a different channel. So that's the typical filing that I would be doing that we have done.

Q. Okay. And outside the clinical study context so with respect to your care and treatment of patients outside of clinical trials, have you prepared any Adverse Event Reports?

A. No, I have not.

Q. You had mentioned the CRFs --

A. Yes.

Q. -- which those, is it fair to describe those as the adverse event that may occur during a clinical trial?

A. No. These are just Clinical Research Forms, CRFs. So anything that goes into that form is what we keep. It could be patient information at their one-month visit or a six-month visit. So those are the patient forms, and that goes in the chart.

The Adverse Event Forms are different forms, and so those are also kept and sent to the Institution Review Board.

Q. Okay. And then do you keep the CRF forms as well for the clinical studies that you perform?

A. Yes.

Q. And those also go to the IRB, is that correct?
A. Not all of them because most of them stay with us. Only the Adverse Event Forms and something specific, then it would go to the IRB.
Q. So if something goes wrong or is adverse, it goes to the IRB. Otherwise, it stays with you?
A. If it goes to the IRB, then it stays with us also and it goes to the IRB. So everything essentially stays with us. Certain things may go to the IRB which would be pertinent.
Q. Do the materials that go to the IRB also go to the FDA?
A. No.
Q. Okay. So that goes just to the IRB?
A. That is correct.
Q. Okay. So if there was an adverse event that occurred during the clinical study, you would send that information to the IRB but you do not send it to the FDA?
A. That is correct.
Q. You had mentioned a couple of times that some of your studies have been I think you describe it as investigator-initiated studies?
A. Yeah.

Q. And just so I'm clear on that, that's a study that you, for example, have initiated as opposed to one of the manufacturers?

A. That is correct.

Q. Okay. And do you have a preference for one over the other?

A. I usually prefer an investigator-initiated study because then I control the outcome. The bias factor is much lesser because it is not a company-sponsored trial, and, you know, there's always an element of bias when there is a company-sponsored trial as opposed to an investigator-initiated study.

But the study that we typically favor or I typically favor which is not even investigator initiated such as the one that I mentioned about the MiniArc study which I completely manage it. It's not sponsored by any company and we do it ourselves, so then the potential risk of bias is the least and since it's not being funded by any particular company with vested interest.

Q. And that's because in your view, it would not be appropriate to have a vested interest in the outcome of the study?

A. It is just a bias that is generated, and sometimes you

have to put it in. Most investigator-initiated studies or sponsored studies are very ethical studies, but, unfortunately, it always comes with a bias, that, okay, this was sponsored by this company, so maybe the results are more favorable to that company.

However, if it is not, then it gives the study a little more authenticity and gives me that little more additional armamentarium to put in that additional sentence which states that this was not a sponsored study and so maybe looks more authentic.

Q. Okay. And if it's not a manufacturer-sponsored study, do they still reimburse you for certain expenses and things?

A. No, they do not.

Q. Okay.

A. They are not even aware that I'm doing the study.

Q. Okay. And on the TVT-Secur study that we talked about earlier today, you had mentioned that there were I think you had said some reimbursements from Johnson and Johnson, is that correct?

A. So there were essentially three studies that I was involved with with the TVT-Secur.

Q. Okay.

A. The first was the initial clinical trial which was

completely conducted by Ethicon.

The second paper that I published was our own data which was not sponsored by anybody, and the third paper which was the TVT-Secur in-office that I think you're alluding to, that was an investigator-initiated study which was sponsored by Ethicon.

Q. Okay. So an investigator-initiated study can also be sponsored by a manufacturer?

A. So the investigator-initiated studies are all sponsored. So it is initiated by the investigator. They submit the proposal to the company, and if the company feels that it is a good study from the clinical standpoint, from the research standpoint, then they accept it. So once they accept it, that means they are willing to fund the expenses of that study.

Q. Okay. And if an investigator study is sponsored by the manufacturer, is there some communication with the manufacturer then with respect to the end points for that study?

A. Yes. Usually, for example, with the Exair study, they wanted to know where did they stand, how much is the enrollment, are we keeping our time lines. So if I

said that maybe by the end of December, we should finish enrollment, then I would be fine, I'd be sticking to the time lines.

So it's a very loose connection. It's not that absolutely we have to do something based upon what they want, but it's tracking what am I doing. I'm not just -- it's not that the study's stopped and we're doing nothing about it. We just want to make sure we're still continuing to maintain the time line that I had proposed.

Q. So you do have some periodic reporting obligations to the company during a study of that nature?

A. Yes.

Q. Okay. I know you have some opinions that we'll get to in a little bit with respect to porosity of mesh.

Have you conducted any studies that are specific to the porosity issues?

A. No, I have not.

Q. Have you published any peer-reviewed literature with respect to, specifically with respect to porosity of pelvic mesh?

A. No, I have not.

Q. Have you conducted any studies with respect to degradation of pelvic mesh?

A. No, I have not.
Q. And have you published any studies specific or, I'm sorry, published any articles specific to degradation of pelvic mesh?
A. No, I have not.
Q. Have you conducted any studies specific to the flexibility or stiffness of pelvic mesh?
A. No, I have not.
Q. Have you published any articles specific to flexibility or stiffness of pelvic mesh?
A. I have not specifically stated or published a paper on flexibility or as you mentioned porosity.

However, in my Prolift+M paper that I had published, I did mention about the change in the porosity and the weight that happens with the Prolift+M as it -- as part of the mesh disappears or it's absorbed which is the Monocryl component of the Prolift+M. And from the -- I believe there was some mention in the discussion about the flexibility of that, of the Prolift+M mesh that I had mentioned.
Q. Okay. Have you done -- have you published any papers that discuss the flexibility or stiffness of TVT or, actually, strike that, of an SUI product?
A. Could you explain?

Q. Sure. I'll rephrase that.

Have you done or published any articles with respect to flexibility or stiffness in a midurethral sling?

A. So if you are specifically asking whether I've done anything to see the tension strength and the measuring of the weights and things like that, I have not.

Q. Okay. Are you familiar with the phrase 510(k) submission?

A. Yes, I have.

Q. Okay. Have you participated in submissions or assembly of materials for a 510(k) submission?

A. No, I have not.

Q. And you have not authored any peer-reviewed articles with respect to 510(k) submissions?

A. That is correct.

Q. Have you ever worked on the design of pelvic mesh products?

A. Yes, I have.

Q. Okay. And in what context have you worked on the design of the products?

A. There is a modification of a particular mesh system that I made so as to eliminate a passage of a trocar, and I submitted the drawings to the company.

Q. Is that -- I think I had read that you have a patent on a product.

Is that the product?

A. No. That's a different product.

MR. WALKER: And I just want to make sure, you know, you don't have to divulge anything that's proprietary or otherwise confidential, okay?

THE WITNESS: Okay.

BY MS. FLAHERTY:

Q. You had mentioned that you had submitted some drawings to a company regarding the trocars, was that correct?

A. Yes.

Q. Okay. And was that company Ethicon?

A. No, it was not.

Q. Okay. Can you state which company that was?

A. It was Coloplast.

Q. Coloplast.

And do you know, have you submitted a patent application?

A. Yes, I have.

Q. Okay. What is the status of the patent application?

A. It is in its provisional patent state.

Q. Okay. Do you know -- I will admit I am not familiar with the patent process, but do you know approximately

how long that process takes?

A. I can hold the provisional patent for a year, and we have just been extending it to see that whether I need to file the final patent or do I just give up the patent.

Q. Okay. And how many years have you held that?

A. Now it's two years.

Q. Two years.

Have you ever conducted any studies on polymers?

A. No.

Q. Have you authored any peer-reviewed articles specific to polymers?

A. No, I have not.

Q. Have you done any bench research specific to polypropylene?

A. No, I have not.

Q. Have you performed any explants or revisions of pelvic mesh products?

A. Yes, I have.

Q. Do you know approximately how many revisions or explants you've performed?

A. Anything specific or just overall?

Q. Let's start with overall, and we can break it down

from there.

A. Maybe about twenty-five.

Q. And just so we're clear, does that include what I would call a trimming that might happen in the office under a local anesthesia, or is that only a surgical procedure with general anesthesia?

A. That includes any explants, whether it's in the office or in the operating room. That includes whether the mesh was used for a sacrocolpopexy or whether it was used for a vaginal prolapse. That includes whether a sling was used for incontinence, and that's includes any possible sling or mesh, whether it is Ethicon or non-Ethicon, and that also includes suture such as Prolene suture that could be sticking into the vagina.

Q. Okay. And when you conduct those explants, do you do any sort of microscopic evaluation of the mesh that you remove?

A. I do not, but sometimes -- I am not sure if I've done that, but I may have sent it for pathology.

Q. So you send it on to somebody else to handle the pathology, is that correct?

A. If I did that, yes.

Q. Okay. Do you have a degree in epidemiology?

A. I do not.

Q. Is it fair to say you would not call yourself an expert on epidemiology?
A. Yes.
Q. Okay. Why don't we take just a five-minute break.
A. Sure.
(Off the record at 10:27 a.m.)
(Back on the record at 10:40 a.m.)
BY MS. FLAHERTY:
Q. Okay, Doctor. We're back on the record, and I want to switch gears a little bit and talk about your treatment of patients with urinary stress incontinence.
And I think you had mentioned was it roughly twenty to twenty-five percent of your patients have urinary stress incontinence, is that correct? Did I get that correct?
A. That is correct.
Q. Okay. And is it fair to say that for at least some of these patients, their incontinence is a quality of life issue for them?
A. Most patients who come to see us usually do that for that particular reason, it is bothering them, and very few would come in just because they've been sent by their physician. But most of them would come for

quality of life issues.

Q. Okay. And you use midurethral slings for treatment of SUI, is that correct?

A. Yes, I do.

Q. And you also have some other surgical procedures that you use for treatment of SUI, is that correct?

A. Yes, I do.

Q. And what are those other surgical procedures?

A. I predominantly use, if it is a surgical intervention, I predominantly use a midurethral sling, and, of course, there are different types of midurethral slings.

However, if it is a patient who has restricted mobility of the urethrovesical junction, then I would use a bulking procedure called transurethral injection of Macroplastique.

Q. Okay. Any other surgical interventions that you would do?

A. For stress incontinence, essentially those are the two main procedures that I would do.

Q. And are there some nonsurgical procedures that you would also try?

A. Yes.

Q. And what are those?

A. First of all, we would start with behavioral modifications just like as I was mentioning, caffeine elimination so as to decrease the amount of urine production.

The second would be timed voiding. Sometimes the patient may be holding her bladder for over four to five hours, and then when she sneezes, she may leak because her bladder is too full. So all she needs to do is go to the bathroom every three hours. So that's timed voiding.

Fluid management. They could be drinking a lot of water as part of let's say weight loss, and that could be creating a deluge in the bladder and the blader may be filling up very fast, and that could overpower the urethra. So then amount of fluid control, restricting fluids to about sixty to sixty-five ounces a day.

So timed voiding, fluid management, elimination of caffeinated beverages, pelvic floor exercises with a pelvic floor training system that we have at our office. So these are the main things that we always talk to our patients prior to embarking onto a surgical intervention.

Q. Okay. Do you also recommend the use of pessaries from

time to time?

A. Very rarely would I use pessary exclusively for stress urinary incontinence.

Q. And why is that?

A. That is, first of all, because it's very incumberent. Number two, the success is not very high. Number three, most patients do not like using a pessary for that reason. So that's predominantly it.

I would typically use it in a patient who would tell me that she has extremely sporadic stress incontinence, only if she is playing golf would she leak. I'd say, okay, you can consider this, or a woman who is desirous of getting pregnant. Then if we tried everything else and finished pelvic floor therapy, it's not working, then I would go on to considering an incontinence ring pessary.

Q. Okay. With respect to the surgical treatment options, is an anterior -- I may not pronounce this correctly -- is it colporrhaphy?

A. Colporrhaphy.

Q. Yeah. Colporrhaphy.

A. That's right.

So an anterior colporrhaphy is not a surgical procedure for stress incontinence management.

Q. Okay. Is a Burch colposuspension?
A. Yeah. You can just say Burch procedure.
Q. Okay.
A. Burch procedure is a surgical intervention for incontinence.
Q. Okay.
A. Stress incontinence.
Q. Do you utilize the Burch procedures?
A. Not at the moment.
Q. Okay. Have you used Burch procedures in the past?
A. Yes, I have.
Q. Okay. Do you know how many Burch procedures you have done in the past?
A. Probably about three hundred or so.
Q. When was the last time you did a Burch procedure?
A. Almost about ten years ago.
Q. Did you stop doing Burch procedures about the time you started using midurethral slings?
A. Yes, I did.
Q. Is needle suspension surgery a surgical treatment option for urinary stress incontinence?
A. It has been reported as a surgical procedure for stress incontinence.
Q. Okay. Have you used this procedure for urinary stress

incontinence?

A. Typically the needle procedure is like the Raz, R-A-Z, or the Pereyra, P-E-R-E-Y-R-A, procedures, and if that is what it is, then, no, I have not used it.

Q. Is a Stamey procedure also a needle suspension procedure?

A. Yes.

Q. Have you used the Stamey procedure?

A. I have not.

Q. And I just want to clarify. On page fourteen of the TVT and TVT-O report, I'll let you get to that.

A. Should I put this away?

Q. You can keep it close, but we don't need it right this minute.

A. Okay. Yes.

Q. And do you see where it says surgical treatment for urinary stress incontinence, probably in the top third of the page?

A. Yes.

Q. And the first item listed is anterior --

A. Colporrhaphy.

Q. Correct.

A. Yeah.

Q. Is the anterior colporrhaphy -- I cannot say it.

A. Anterior repair.
Q. Anterior repair. Thank you.
So just to clarify, you said that is not a surgical treatment for urinary stress incontinence?
A. That is correct.
Q. Okay.
A. However, what they are probably alluding to is what is often called an anterior colporrhaphy with Kelly plication.
Q. Okay.
A. So Kelly plication is where a suture is placed at the bladder neck, and that is -- that was one of the main operations for stress incontinence at that time, so probably in the forties to the sixties, and Howard Kelly who was considered the father of urogynecology devised this particular technique.
However, nobody else could enjoy great results with this, so it gets lumped around with anterior colporrhaphy. Anterior colporrhaphy per se is a procedure for anterior vaginal wall prolapse, not incontinence.
Q. Okay. And you had indicated that they used it.
I just want to -- who are you referring to as they?

A. Gynecologists.
Q. Okay. Gynecologists during that time period?
A. Yes.
Q. Okay. And have you ever used the anterior repair with Kelly plication?
A. Yes, I have.
Q. Okay. Do you still use that procedure?
A. I do perform anterior colporrhaphy for vaginal wall prolapse, but I do not do a Kelly plication.
Q. Okay. And the Kelly plication would come in if there was urinary stress incontinence?
A. That is correct.
Q. Okay. And just an overview of the nonsurgical treatments for urinary stress incontinence, you talked about pelvic floor muscle therapy which you offer in your office?
A. Yes, I do.
Q. And the pessaries?
A. Yes.
Q. And behavior modification, and that included things such as limiting caffeine, timing of voiding, is that correct?
A. That is correct.
Q. Okay. And then also the bulking agents?

A. Yes.
Q. Are there any other nonsurgical options that you recommend with respect to treatment of urinary stress incontinence?
A. Yes. I do also based upon sometimes weight, if a patient is obese, then I would recommend that weight loss has clearly been shown to improve incontinence. So that's something I would recommend and also things like smoking cessation because smoking can cause several factors, especially coughing would increase the risk of the pelvic floor and stress incontinence. So depending on what is the patient's medical history, then I go by that.

Sometimes patients are taking medications such as lisinopril which is classic medication for high blood pressure. That medication causes a side effect of coughing, and then if they're taking that and they're coughing, that could be causing stress incontinence.

Sometimes patients have it because of weight or neck issues, they may be snoring, and they may have something called obstructive sleep apnea, and if they have that, then it's almost like straining when you're obstructing, so they may be leaking urine.

So what they may need instead of getting a sling is just a CPAP machine, and that could take care of the leakage.

So there are many factors based upon the medical history of the patient that I may be addressing that could help with the incontinence. It could also be that she may be taking a diuretic, and we may just have to change the timing of the diuretic.

Q. Okay. And so to summarize, it sounds like you have a conversation or it's your usual practice to have a conversation with your patients and examine a variety of factors with respect to their urinary stress incontinence, is that correct?

A. Yes. So what we do is we give the patients several validated questionnaires and a history form which is almost like a little booklet as they complain because it's a lot of forms that they have to fill out, but it is extremely helpful to us to understand what exactly is their overall perspective that they may not even have realized could impact their complaint.

And when we look at those aspects and the history and review everything with the patient and then we have this conversation with the patient, then we can appropriately come to proper management

options.

Q. Okay. And during that conversation, is it your usual practice to have a conversation or a discussion with the patients regarding the risks and benefits of the various options?

A. Yes.

Q. Okay. What percentage of your SUI patients require surgical intervention?

A. I would say in between seventy-five to eighty percent, but, you know, it's hard to say. This is just a guess because I have not really studied that and seen how many patients actually go for surgery because our typical, our typical course when we see a patient with stress incontinence is we go over all these things, and then we leave it to the patient to decide based upon the risk-benefits profile and what she feels is the best option for her. So she may choose surgery or she may choose otherwise.

Q. Sure.

A. And so then we respect what their decision is based upon what we think would also be good for her.

Q. Understood.

And with respect to the surgical repair or surgical treatment of SUI, is it fair to say that the

majority of your surgical repairs at this point in time involve a midurethral sling?

A. Yes.

Q. Okay. And I believe your report had broken down, I think it says you had performed maybe one thousand or so surgical repairs with respect to SUI over the course of your career?

A. Yes.

Q. And I think there were roughly three hundred of those that were TVT-Secur.

Does that sound about right? I probably have the number. I can find it in your report. Let's see if I can find the page.

A. It's a hundred TVTs, four hundred TVT-O, and three hundred TVT-Secur.

Q. One hundred TVT, four hundred TVT-O, three hundred Securs?

A. Yes.

Q. So that's roughly eight hundred sling procedures?

A. Roughly.

Q. At least with Ethicon products?

A. Correct.

Q. And with respect to the other approximately two hundred surgical procedures, what percentage of those

involve other types of midurethral slings?
A. Almost all of them were other types of midurethral slings.
Q. Okay. Aside from the TVT, TVT-O, and the Secur, what other types of pelvic mesh slings do you use?
A. Suburethral slings?
Q. Yes.
A. I have done the MiniArc suburethral sling and the Solyx, S-O-L-Y-X.
Q. Is Solyx a Boston Scientific product?
A. Yes.
Q. Do you still use the MiniArc and Solyx?
A. MiniArc is no longer available, and I still use the Solyx.
Q. Okay. And is Solyx a retropubic transobturator approach?
A. It is a single-incision sling.
Q. Okay. And the TVT-Secur was a single-incision sling, wasn't it?
A. That is correct.
Q. Did you switch to the Solyx after the TVT-Secur was no longer available?
A. I switched to the MiniArc which is a single-incision sling.

Q. Yes.
A. So I have maintained the single-incision sling as part of my practice. That's my primary surgical intervention.
Q. Okay. And so you went from the Secur, when that was no longer available, you went to the MiniArc. When that was no longer available, you went to the Solyx?
A. That is correct.
Q. Okay. And you've done about four times as many TVT-O procedures as opposed to TVT.

Is that because of the approach that is used with the TVT-O procedure?
A. It is just the timing. So when the TVT initially came out, I was still in my fellowship, and I was doing the Burch colposuspensions. Then we were doing a study on laparoscopic Burch colposuspensions. So we were focusing more on that, and this was around the late 1990s.

And then very shortly thereafter, I believe it is 2007 or 2008 when -- 2011 when the TVT-O came out. So I immediately, I was one of the first persons who started using it because I had trained in France, same place where Jean Delavalle had, he was from Belgium, but his associate, Doctor Jacques Thayer, was

in the same hospital.

So I had contacted him and he had advised me this is a very good technique to perform, it goes along the natural fascial supports of the urethra which John Delancey from the University of Michigan had described as the hammock hypothesis. So it sounded to be more of a natural support for the urethra because that's where it's coming from.

So I thought that might be a good option to go by, and once I started doing it, I somehow starting having good results. I continued doing the transobturator procedure.

Q. Okay. And just so the record is clear, I suspect both know and I know what we're talking about, transobturator mesh is the TVT-O?

A. That is correct.

Q. Okay. And TVT is the retropubic approach?

A. That is correct.

Q. Okay. Now, in your TVT and TVT-O report, you indicate that the retropubic approach offers a slight advantage over the transobturator approach in terms of cure rates. That's on page twenty-three of your report.

A. Which paragraph?

Q. Let's see. The second paragraph on page twenty-three.

It starts with: Overall, these data suggest that the retropubic approach.

A. It has, yes.

I'm sorry. What's the question?

Q. Sure. Is it your opinion that the retropubic approach has a slight advantage in terms of objective cure rates over the obturator approach?

A. No.

Q. Okay. So is that -- I just want to make sure I understand that statement in your report.

That's not your opinion. Is that just a summary of the data that you were reviewing?

A. Yes.

Q. Okay. And then the next sentence states that --

A. Could I clarify?

Q. Sure.

A. This data essentially states that the retropubic approach offers a slight advantage over the transobturator approach in terms of objective cure rate.

So we look at overall cure rate and the subjective cure rate, there was no difference, but in certain studies, the objective cure rate may have been slightly better with the retropubic than with the

TVT-Secur.

Q. Okay. And how do you distinguish between the objective cure rate and the subjective cure rates?

A. So the subjective cure rate is essentially what the patient states. Usually that is conducted through validated questionnaires that they fill out before and after.

The question could be in a validated form do you leak urine with coughing, laughing, or sneezing, and she may have said yes or no, and how bothersome is that, and she may have mentioned yes initially and she may have said greatly bothersome.

Postoperatively the same question is asked, do you leak with laughing, coughing, and sneezing, and now she may say no, so then that's a subjective change. So you say how many patients said yes, how much patients say no, and look at what the difference is, and then you can see the percentage change in that particular subjective questionnaire. In some studies they may just ask the patients how are you doing. So it all depends on how the question is formatted.

Objectively, typically it is a cough test which is usually done at a standard amount of bladder fullness or when the patient feels subjectively full,

or it could be in the form of a pad weight test. So preweighed pads are given to the patient. She walks around either for an hour, she changes it, or for a day, and then she puts it back in a Ziploc bag and brings it back to the office, and then we weigh it and we see what is the difference in the weight in grams, and based upon the difference, we can state that this is successful or not.

Q. Okay. And so to summarize that, there's a functional component of the analysis as well as perhaps the patient's interpretation or quality of life view with respect to the results as well?

A. So functional, yes.

Q. Okay. And this goes on then to state that the two approaches have different adverse effect profiles but with the retropubic approach or with -- I'm sorry -- with the retropubic approach causing a higher rate of perioperative complications.

Has that -- is that your opinion that the retropubic approach has a higher rate of perioperative complications?

A. No.

Q. Okay. Do you -- in your opinion is there a difference between the retropubic and transobturator approaches

with respect to complications?
A. There's no difference.
Q. And what is the basis for that?
A. The subsequent studies that I've quoted, especially by Tommaselli, T-O-M-M-A-S-E-L-L-I, and Ford, F-O-R-D. So they have basically looked at this and shown that ultimately there is no significant difference. The numbers are very similar. Whether it is bladder injury you're looking at or voiding dysfunction or pain, they're very similar.

And that also, these are good studies which are published in the literature, plus my own experience having done the TVT and having done the TVT-O, I've seen that there is really nothing that stands out.
Q. Do you -- after your patients have a surgical procedure, specifically a midurethral sling, do they continue to treat with you after, after that procedure and perhaps after the initial recovery period?
A. We have a very strict format in our office because we do clinical trials. So whether patients are part of a clinical trial or not, we almost always insist at the presurgical appointment that the patients need to follow up, and we tell them that there's a certain

period of follow-up. Usually it's at six months postoperative, one year postoperatively, and maybe then two years either on the phone or at the office.

And we do not charge for these visits. So this is more to see how are these patients doing and for us to understand what is the long-term outcome and how these patients have been doing ongoingly.

Q. Okay. And if the patients don't follow up, do you reach out to them to try to get them back into the clinic?

A. Yes.

Q. And I know you had mentioned again the clinical studies.

Do you have a sense for what percentage of your patients are part of a study versus what percent are coming to see you outside the scope of one of your studies?

A. We try to almost put everybody in some kind of a clinical study or preparing for a clinical study. So she may not be enrolled in a clinical study for now, but we may use her data in another study which could be a study done postoperatively, almost like a retrospective study. So if it is a retrospective analysis, as long as the data is prospectively or

properly collected, then we can fall back on that data in the future.

Since I have a fellowship and, you know, the fellows are obliged to come up with papers, it is important to continue to keep publishing. So it is good to collect the data. We never know when the data would be useful. Just like when in 2008 the FDA came out with the initial warning and said that this may be a problem, we had enough data to fall back on and see our other clinical trial and see what was our outcomes.

So just like what MDS proposing to talk to the patient about your outcomes, we can now knowledgeably talk to our patients about our own outcomes and tell them what are the facts.

Q. Will you treat patients if they aren't part of a clinical study or decline to be part of a clinical study?

A. Yes. So, again, I'm sorry. Most patients, they're not all part of a clinical study, but we try to get all the papers.

So if a patient were to say I do not want to fill the forms out, we try to explain to them the value of that for themselves and for women at large,

and if they still decline, then we will still manage them.

Q. Sure.

And if you use it in -- if you use the data in a retrospective analysis, is that something you have to go back to the patients and gather their consent, or is there a different process for that?

A. For that we do not have to get a consent. It's a chart review. As long as we have the information in the chart, we can just review the chart, and the patient's information is, of course, blinded.

Q. So they wouldn't necessarily know it's being used for that purpose later, but their individual identifying data is not shared?

A. Correct.

Q. Okay. Do you -- I think you had said you have done maybe just twenty to twenty-five surgical repairs of mesh that was previously implanted, is that correct?

A. Explants.

Q. Explants?

A. Yes.

Q. Are there other types of surgical repair that you might do for mesh?

A. Yes.

Q. And can you describe that for me, please?
A. If I've done, for example, one wall mesh and then the contralateral wall falls down, then I may go back and repair the contralateral wall. So it is recurrence of the contralateral wall prolapse or recurrence of the treated wall prolapse.

For stress incontinence, it could be that I've performed a sling on a patient, and now she has ongoing stress incontinence. Then I may go in and do a modification of that sling or put another sling in. So those are the typical things I've done.

In the past I've also done where the sling was too tight, then I had to release the sling. So these are procedures that could be done for different reasons.

Q. Okay. And do you have occasion to treat patients that were implanted by other physicians that may now have some complications with respect to their mesh?
A. Yes.
Q. Okay. And would those patients be included in the explant procedures that you just described?
A. Yes.
Q. Okay. Are there patients that actually -- strike that.

In the explant procedures, were you able to remove all of the mesh?

A. I have never had to remove all of the mesh.

Q. Okay.

A. Ever.

Q. Okay. Would you agree that dyspareunia is a complication that's been reported with respect to both the transobturator and retropubic slings?

A. I do not agree that dyspareunia is a cause of the or as an outcome of the sling, but it has been reported in papers published on slings.

Q. Okay. And is it your opinion that the dyspareunia is caused by something other than the sling?

A. Yes.

Q. Okay. And what in your view causes the dyspareunia?

A. There are many factors. One key thing to note is did the patient have -- is it de novo dyspareunia or is it ongoing dyspareunia. So for that it is very important to document whether the patient had this before a procedure was done, whatever that procedure could be. So that's important.

Number two, she could have a condition called underlying pelvic pain syndrome. There could be postmenopausal vaginal atrophy. There could be

previous surgical procedures done that could have resulted in scarring that could be causing pelvic pain.

There could be so many factors, it could be a male, female disparity, you know, and whether it's the same partner, different partner, whether it is psychological, nonpsychological. So there are so many, so many factors that could play a role in dyspareunia.

Q. Would you agree that erosion of the mesh can contribute to dyspareunia?

A. No. It does not contribute to dyspareunia. I disagree.

Q. So in your view, you would disagree with anyone that would associate dyspareunia with extrusion or erosion of mesh?

A. Yes, and I can explain why. It is the mesh where it is placed in the vagina, it's already placed. Whether the skin or the epithelium under that heals or remains open does not change the configuration of the mesh in the patient's body. It remains as is.

Many a times if there's an exposure, this could be managed expectantly. Fifty percent of the times the mesh exposure does not have any symptoms and

does not need to be removed.

The typical complaint that I have seen patients come with mesh exposure is not dyspareunia. It is either vaginal spotting or more likely it is hispareunia, meaning he, her partner, feels something in the vagina that is sharp. And then if you feel this thing and, yeah, that is what is causing it, and then we may have to take care of that exposure.

But the patient almost never feels that as a cause of dyspareunia because it's already there. Whether the epithelium under that heals or not, it doesn't remove the mesh as such. So if it has healed below it and there is no exposure whereas if it's open, that doesn't make a difference from the point of view of the patient.

Q. And you have not analyzed any of the mesh material that has been removed from women in terms of any degradation or change in consistency of that mesh from a pathologic point of view, have you?

A. I have not analyzed mesh.

Q. Okay. And you would agree that groin pain is a complication that's been reported with respect to midurethral slings, is that correct?

A. Yes.

Q. And you would distinguish between I think what your report refers to as transient versus chronic groin pain, is that fair?

A. Yes.

Q. And would you agree that a chronic pain is something that's going to have perhaps a more significant impact on a woman's quality of life?

A. Well --

MR. WALKER: Object to form.

THE WITNESS: Even a transient pain could have some impact on quality of life because even if it's there and it's hurting her, it's hurting her. So the only thing different between transient and chronic is chronic has been ongoing for quite some time.

Typically the definition varies what chronic pelvic pain or chronic groin pain may be, but usually it's attributed to usually lasting more than six months which is an ongoing process.

BY MS. FLAHERTY:

Q. Okay. Do you -- actually, strike that.

When we were talking about the surgical operations for SUI, just to step back, I think I forgot to ask you about this. Is another option the fascial sling?

A. Yes.
Q. And that's different than a Burch procedure, correct?
A. That is correct.
Q. Okay. And have you performed any fascial sling procedures?
A. Yes, I have.
Q. Okay. Is that something that you utilize for certain patients?
A. Extremely rarely at this moment in time.
Q. Okay. And why is that?
A. It is too invasive to perform, especially if you're using an autologous fascial sling because you have to the harvest either the fascia lata, L-A-T-A, which comes from the side of the thigh, so you take a strip from the thigh and then put it under the urethra, or you harvest the rectus fascia which is from the lower belly and put it under the urethra. So it's a very involved operation for something that can be managed minimally invasively.
Q. And when you say that, you mean via the midurethral sling?
A. That is correct, synthetic midurethral sling.
Q. Yes. Do you use any biologic products for treatment of SUI?

A. The only thing I would use is the Macroplastique, it's partly biodegradable, but not for a sling.
Q. Okay. And why is that?
A. Because the data that has been published on biologics has been very poor with significant failure rates, and I have overall been very happy with the use of midurethral slings using a synthetic material, and it has stood the test of time.
Q. I want to talk a little bit about training with respect to the pelvic mesh products, specifically the midurethral slings.

Your opinion indicates that you have and your testimony earlier today have indicated you've participated in quite a bit of training with respect to the various Ethicon sling products, is that accurate?

A. As a proctor or teacher?
Q. Yes.
A. Yes.
Q. And do you know about how many hours you have spent teaching or proctoring with respect to sling products?
A. Just the Ethicon you're talking about?
Q. Let's start with Ethicon.
A. I know that's way back. As I mentioned, I do not

think I've done anything since 2008.
Q. Okay.
A. So it's way back, so it will be total conjecture for me to think about how many hours.
Q. And you've also done some proctoring with respect to other companies' mesh products, is that correct?
A. Yes.
Q. And we'll focus just on slings for right now.
A. Okay.
Q. And then did you mention earlier that you had trained in France with some doctors on midurethral slings?
A. Actually, I trained in operative laparoscopy, but the next hospital was the main hub of their French Urogynecology Society. So I met him, but I had not trained with him.
Q. Okay. Did you participate in any meetings or have the opportunity to maybe take advantage of having that proximity to that additional training?
A. Yes.
Q. Okay. And in addition to the proctoring, I assume before you did that, you probably attended some of the training sessions so that you yourself could learn about the implant process for the TVT products?
A. Yes.

Q. And can you -- do you recall how much training you received prior to implanting your first TVT product?
A. You know, that will be way back. So it would probably be like 1990. So I don't even remember if my -- I think it was I was in my fellowship. Doctor Bent, B-E-N-T, was my fellowship director, and I believe he had just started doing the slings, and he was training me as his fellow.
Q. Okay. So did you also attend any cadaver training prior to implanting TVT products?
A. Yes, I did.
Q. Okay. And did you at some point while you were proctoring, did you -- was that also done in cadaver labs?
A. Yes.
Q. And did you also have occasions where other doctors could come in and observe you during surgical implantations?
A. Yes.
Q. And what other types of training did you conduct for doctors who were wanting to learn about the Ethicon midurethral slings?
A. You know, I was on their advisory board in the sense that if a doctor had any question, they could e-mail

me or ask, call me and ask me specific questions in that regard. So I may have had a few calls from doctors in the field who were asking questions about what may have happened or how they could improve the process.

Then I used to go to the Ethicon-driven Summit meetings they would call it, and those were held annually, very good networking meetings where physicians would come together and we would brainstorm each other and there would be breakout situations, and I have sometimes led the TVT-Secur or the Prolift+M breakout session. But, again, these are physicians who are practicing, so then we would learn from each other.

Q. And in the advisory board, just so I'm clear, is that an Ethicon advisory board, or what type of board is that?

A. It's not an advisory board. It's just some physicians who they are main proctors, and they could bounce some questions by them. So if a physician had any question, they would ask the proctors.

So since I was one of the proctors, I had agreed to have doctors call me, especially doctors who had come to my site and trained with me or doctors who

I had trained at cadaver lab, and they went out and started practicing and had some outstanding questions, I would field their calls.

Q. Do you recall, how long did you serve in that capacity?

A. I was open to them, so there's no set rule, there is no financial agreement to do that. It was just a courtesy for my colleagues so if they had to call me, they could call me any time.

Q. Okay. And the Ethicon-driven Summit meetings, is that what they were called?

A. Yes.

Q. And those were annual meetings for physicians?

A. Yes.

Q. And then were there Ethicon representatives there as well that could answer questions regarding the various products?

A. Yes, but it was mainly aimed at physician interaction, physician-to-physician interaction.

Q. Okay. And did those occur at various locations each year?

A. Yes.

Q. Okay. And did you prepare materials for those Summit meetings?

A. Yes.
Q. And are those materials that you would then present or share with the other physicians that were attending?
A. Yes.
Q. And did Ethicon have any role or did you -- did they review any of those materials that you prepared for the Summit meetings?
A. No.
Q. Do you still have copies of the materials that you would have used?
A. No.
Q. Were you paid for any of your time at the Ethicon Summit meetings?
A. Yes.
Q. Do you have any invoice or other documentation regarding the compensation you would have received during that time?
A. No. Again, this was probably on the 2004 to 2006 time frame.
Q. Okay. And is it fair to say that that information would or at least should be included in the 1099s that you've received over the years from Ethicon?
A. Yes.
Q. We've been talking lots about the three different mesh

products, and I just want to confirm.

With respect to TVT and TVT-O, is it your opinion, Doctor, that the mesh is the same, the approach is different but the mesh itself is the same?

A. It may have been changed. Some slings are cut mechanically, one is laser cut, you know, so that may be different. But otherwise it's essentially the same.

Q. And with respect to the laser cut versus mechanical cut, do you have a preference for which one you use during your procedures?

A. No, I do not.

Q. Do you make a request to have laser cut versus mechanical cut?

A. No, I do not.

Q. Okay. And do you know what percentage of the mesh you use is mechanical versus laser cut?

A. Well, now I believe -- I don't know what the present mesh is on the sling is, but I believe that it is cut, almost all are laser cut, but the TVT-Secur that I used finally was a laser-cut mesh.

Q. And we talked a little bit about you had attended cadaver lab and I think some other proctor session.

Was there any other training that you

received prior to implanting the TVT devices?

A. The TVT-Secur I had to go to cadaver lab at Ethicon because it was the first time that they were launching this. So that was the -- and then that was the only thing. No, I have not gone to anybody else to train.

Q. Okay. So on the TVTs and the TVT-Os, what was the training that you received prior to implanting those devices?

A. TVT was most likely with my fellowship director, Doctor Bent, and the TVT-O, I don't recall if I went anywhere. I know I went to a cadaver course, but I'm not sure if I went to -- I think 2002 I believe. I don't even remember where I went, if I went to someone to watch him or her operate.

Q. Prior to using the TVT and the TVT-O, were you using other manufacturers' midurethral slings?

A. I don't think there existed any. No, I was not.

Q. So the first midurethral sling you would have used would have been the TVT?

A. Synthetic one, yes.

Q. Were you required to observe a certain number of procedures before you were able to implant a synthetic midurethral sling?

A. Since I was already doing it as part of

sacrocolpopexies, we were already using synthetic material for prolapse. So that was part of my training.

And then as part of my fellowship, I was already being trained to using the TVT product.

Q. So there wasn't a certain number of procedures you were required to observe?

A. Yeah, I don't recall any such number.

Q. Did you assist in drafting any of the training materials that Ethicon used to train other physicians in the use of synthetic midurethral slings?

A. Yes, I did.

Q. Okay. And what was your role in drafting those materials?

A. It was a surgeon monogram that we put together for the TVT-Secur. So we were -- so people who had enough experience with the TVT-Secur and had good results were invited to participate in this meeting, and when we got together, we fielded some potential concerns and questions that Ethicon may have heard from physicians.

And having done several of these, we could understand where these concerns were coming from, and, therefore, we tried to come up with certain set

guidelines to help surgeons improve their outcomes. So that was the goal of that monogram.

Q. Okay. And so that was after the TVT-Secur was on the market, and you were trying to help perhaps further clarify or explain some of the issues or how to address issues that physicians were experiencing?

A. That's correct.

MR. WALKER: Object to form.

BY MS. FLAHERTY:

Q. Okay. And you had mentioned a monogram.

Can you describe for me what a monogram is?

A. It is a booklet that we have put together, and that's basically what it was.

Q. Okay. So that's something that's in addition to or different from -- actually, strike that.

The monogram is not the IFU, Instructions For Use?

A. That is correct.

Q. Okay. And I believe I had -- are you familiar with the phrase, I think it's Tips and Pearls --

A. Yes.

Q. -- with respect to Ethicon products?

A. Yes.

Q. Do you recall if there was a Tips and Pearls document

with respect to the TVT-Secur?
A. Yes.
Q. Okay. Is that part of the monogram that you just described?
A. I believe so.
Q. Okay. And the intent behind those was to help perhaps further clarify the information that was in the IFU?
A. It was mainly to help --
MR. WALKER: Object to form.
THE WITNESS: It was mainly to see what are the technical differences between the slings that were being done before and now, and that was a major problem that surgeons were not able to get over the fact that these are no longer long slings, this is a short sling, and how do you actually place it.
And the value of placing was so important because what we realized is that the entire tension was being directed to us thinking, oh, this is a small little incision in the vagina, it's very easy to do this procedure.
In fact, it was very -- it was harder to do the procedure as compared to a TVT or a TVT-O because you had to absolutely make sure that if you're going by the hammock approach, you're actually getting into

the muscle. With a TVT-O, you are going through the muscle. There is no question about that because you're coming out to the skin and so you know that you have gone through the muscle whereas here if you do not angle it correctly, you are not getting into the muscle. So those were important features that we realized.

At the same time, you know, how do you lay the sling. It is a pull-out technique, it's not a pull-up technique. That was a huge difference for us to understand. So rather than leave an instrument because throughout what we had learned, and surgeons had done hundreds of these operations, maybe thousands, leaving an instrument between the sling and the urethra at the time of tensioning.

So all of us were used to leaving a little bit of a gap there. But with the Secur if a gap was left, that was bad news, and that is why even I had initial failures with the TVT-Secur.

And then I realized that, no, this is a problem of my technique, and as I got better and better at it, I realized that this is a different type of placement, you know, than the TVT and the TVT-O, and that is what we wanted to explain and make the

other surgeons understand.

BY MS. FLAHERTY:

Q. Okay. And that's because it was important to make sure that doctors understood the proper implantation technique for the product?

A. That is correct.

MR. WALKER: Object to form.

BY MS. FLAHERTY:

Q. And the monogram which I think is -- actually, strike that.

And the monograms were necessary to help further explain that process for physicians?

MR. WALKER: Object to form.

THE WITNESS: So if physicians felt the need that they were having some issues, and then it was more to highlight, once the material, once the device was in place for some time and then what did we find. So obviously there's no way we can find outcomes in three months, what happened at six months out, what happened at a year out, and then why if, at all things, were not going right, what was happening.

So many of us realized over time, and that's the only way to learn, because information for use will not tell you what is going on because that's

initially set, and then as we go on, we say what did we learn from clinical experiences, what did we learn from our peers, what did we learn from what is published, and based upon that, we came up with these different notions and ideas and we put together in there what you mentioned, the Tips and Pearls.

BY MS. FLAHERTY:

Q. Okay. So it sounds like the implantation technique and the tensioning were factors with respect to the outcome for a particular patient or doctor?

MR. WALKER: Object to form.

THE WITNESS: From the point of view of the TVT-Secur, it's very important to do it correctly, and if it was -- if the procedure points that are highlighted in let's say the IFU, they're mentioned there but they had to be stressed, the value of doing this correctly.

So, for example, the IFU say not too less tensioning, not too much tensioning, you know, what does that clinically mean, so how does a doctor understand those things.

So ultimately if I'm out there, if I'm out there as a doctor who is practicing and I want to know what to do, how would I go about it is to look at what

is published, what other information comes out, and usually it is mostly I would get some publications.

And in a paper that we published, we even highlighted in the discussion the value of this pull-out technique and how the sling should be positioned as opposed to the previous slings.

BY MS. FLAHERTY:

Q. And the monograph is one of the things that would help physicians understand this and highlight the importance of this as you just mentioned?

A. Yes, one of the things.

MR. WALKER: Object to form.

BY MS. FLAHERTY:

Q. Okay. Did you assist in preparation of any of the training materials with respect to the TVT or TVT-O?

A. No, I did not.

Q. Okay. Do you need a break? It's been about another hour.

A. No. It's up to you.

MR. WALKER: Can we go off the record real quick?

MS. FLAHERTY: Yeah.

(Off the record at 11:29 a.m.)

(Back on the record at 11:38 a.m.)

MS. FLAHERTY: Back on the record.

BY MS. FLAHERTY:

Q. Doctor, in your TVT-Secur report which is Exhibit No. 5 --

A. Yeah.

Q. All right. On page twenty-seven, you indicate that the TVT-Secur was developed because of dangers associated with the TVT and TVT-O, is that correct?

A. Could you -- which line is that?

Q. Sure. Let's see. On page twenty-seven, see where it says genesis and rationale for the TVT-Secur system?

A. Yes.

Q. And the second paragraph, it says: The main risks of the retropubic TVT passage are bladder injury and injury to blood vessels.

A. Uh-huh.

Q. Some of these injuries, especially to blood vessels, can be catastrophic.

A. Uh-huh.

Q. And you would agree with that?

A. It depends on the placement. So if the surgeon does not follow the typical technique of placement of a TVT and sort of goes lateral, then they could hit the external iliac vessels, and that has happened,

especially if they deviate from the normal method of doing it, and that could be catastrophic.

Q. And you go on to say that the elimination of trocars could help with these complications or help prevent these complications I think is what it says.

A. Potentially.

Q. Potentially.

Okay. Are there additional potential dangers associated with the retropubic approach aside from the bleeding that we just described?

MR. WALKER: Object to form.

THE WITNESS: Are you talking about retropubic TVT sling?

BY MS. FLAHERTY:

Q. Yes.

A. So any surgical intervention has possible complications, whether it is a device or non-device, and typically would be bleeding, infection, and injury is the three things that we typically always quote. So bleeding to the neighboring vessels could happen, and you never know, there could be a vessel in the space of Retzius that could bleed.

Second is injury. Even if you try to deflect the bladder to the contralateral side, there

may be scarring from a previous operation that the patient may have had, and there is possible risk of injury to the bladder and possible risk of infection because you are working in the vagina which has a bacterial flora. So that's why it's called a clean-contaminated surgery.

So there's always a possible risk of these three factors.

Q. Would you also include in the risks or, I'm sorry, in the list of potential dangers associated with the retropubic approach bowel perforation?

MR. WALKER: Object to form.

THE WITNESS: If a sling is done correctly, then it is very, very unlikely to happen, and it is even in reports published, I mean, they don't even mention it because it could be like one or two cases over maybe a hundred thousand.

So typically I would not even discuss with my patient, though I may say that that could happen, it's very rare. You can't even give a percentage to that complication.

BY MS. FLAHERTY:

Q. What about bladder perforation?

A. Bladder perforation is just the way you're going in,

and it's impossible to say whether it could hit or not. That's why it's always good to look inside the bladder, but the risk of that is very low. Typical reports would say less than two percent likely risk of bladder injury with the TVT.

And it has not changed whether it's a TVT or the transobturator. So one may feel that potentially bladder perforation is lesser with a transobturator but could even happen with a transobturator technique.

Q. Okay. So it could happen with either technique?

A. Yes. And it also could happen with a Burch colposuspension. So any incontinence procedure, even a Kelly plication, could cause bladder injury.

Q. Okay. And is that something that you would discuss with your patient before they make a decision as to which treatment option may be best for them?

A. So when we discuss about a surgical modality, then I would talk to her about what surgical modality and what are the potential risks associated with that.

But most of the complications could happen with any anti-incontinence procedure, whether it involves a sling or otherwise.

Q. Okay. And vaginal extrusion, is that an additional

complication that you would discuss with your patients?

A. I would mention that it could happen and there is a potential likelihood of it happening, but that, again, depends on so many factors.

I do not believe -- in my opinion based upon reasonable degree of medical certainty, a sling does not cause erosion or exposure.

Q. The women who have had slings, you're aware that women who have had slings placed have suffered from vaginal extrusion?

MR. WALKER: Object to form.

THE WITNESS: Vaginal exposure or extrusion as you mention is a phenomena where the vagina doesn't heal under the sling, and the sling is then seen or exposed. So that is not a complication of the sling, but it has happened, I agree.

BY MS. FLAHERTY:

Q. Okay. And would you agree that women who have had synthetic midurethral slings placed have also suffered from urethral erosion?

MR. WALKER: Object to form.

THE WITNESS: Could you please repeat the question?

BY MS. FLAHERTY:
Q. Sure. Would you agree that women who have had synthetic midurethral slings placed have suffered from erosion of the mesh?
MR. WALKER: Object to form.
THE WITNESS: I would agree that erosions have been reported in patients who've had some type of a synthetic midurethral sling placed.
However, it is not because of the sling that the erosion has happened.
BY MS. FLAHERTY:
Q. And is it your view that that is caused by other mechanical issues with respect to the patient?
A. There could be many factors. It could be patient factors, it could be the surgeon factors, it could be, you know, the technique, how it was placed, and a part of the patient factor also, what previous operations she had undergone, how thin is the tissue under the urethra, and then, again, you know, what was the tensioning that the surgeon placed under the urethra.
Q. And the tensioning is an important piece of the implant procedure, is that correct?
A. From the success standpoint, yes.
Q. Okay. And when you talk about the success standpoint,

does that also factor in any complications or adverse consequences that a patient may have following the procedure?

MR. WALKER: Object to form.

THE WITNESS: In what sense?

BY MS. FLAHERTY:

Q. Well, you had talked about it factors into the success of the procedure.

Does your definition of success with respect to a midurethral sling procedure include both whether it stops the incontinence as well as whether there's any sort of complications that that woman is suffering following the procedure?

MR. WALKER: Object to form.

THE WITNESS: That's a good question. So, now, in the past, the typical success was based upon certain factors just like as we talked about earlier, subjective cure versus objective cure.

Now, you know, the NIH consensus is, the NIH consensus is that it should not be based upon that. It should be a composite score, it should be how is, how is her quality of life. In other words, yes, you put the sling in, she's not leaking, but how is she voiding, is it too tight that she's not voiding

properly and she's struggling to empty her bladder.

So you want to make sure that you get a composite score which looks at not only how well it has treated the problem that she came for but you did not give her any new problems thereafter.

So when we published our paper on the TVT-Secur in-office, we actually looked at a composite score where we looked at not just how our success was and how dry she was but also did she get any other problems with it. So we put all that together and then came up with a score.

BY MS. FLAHERTY:

Q. If the TVT-Secur was still on the market, would you -- would it be your preference to use that product over the TVT or TVT-O?

A. I would. I had transitioned from the TVT-O on to the TVT-Secur, and the only reason I stopped doing the TVT-Secur was because it was taken off the market. Otherwise, I was very happy with how it was going, and especially with my patients that we were following up were doing excellent with the technique.

And, in fact, I switched to a similar family of operations. So I did not go from the TVT-Secur back to the TVT-O. I went from TVT to Secur

which is a single-incision sling to another single-incision sling made by a different company which is the MiniArc.

Q. And then you went to the Solyx?

A. Which is a single-incision sling. So, in other words, if TVT-Secur was still to be on the market, I would still be using the TVT-Secur.

Q. Okay. And that's because you felt that the success rate was better than what you had experienced with TVT and TVT-O?

A. No. My success was very good with the TVT and the TVT-O. I felt that because it was minimally invasive, I could do it under local anesthesia, and that is why I did a clinical trial in the office. So in that study when we did it, we had a properly formatted trial that we did it where we performed fifty patients in the office completely under local anesthesia.

So what I thought is that it would be a boon for women where now they do not have to go to a hospital, they do not have to go to a surgery center, they could come to a doctor's office, in a methodic and a proper fashion, a procedure should be done, and she is home within an hour and back to work the next day.

Because in our clinical trial, when we did a proper pain scale, patients did not take any narcotics. If anything, they took Tylenol for pain.

Q. Is the Solyx also -- is the Solyx implant also done in the office?

A. I have -- I'm doing it under, entirely under local anesthesia, but since I'm working on my patent procedure, I have not moved it to the office yet.

Q. Do you agree that the TVT, and I'll say TVT, TVT-O, and TVT-S, those implants cause a foreign body response in the woman?

A. Any foreign body which is implanted would cause a foreign body response. So, yes, they would cause a foreign body response.

Q. And those products can also cause chronic inflammation?

A. I do not agree with that. There has been no -- well, actually, let me take it back. It is possible it may cause some type of a macrophage response, but it has never been studied in situ where everything is intact whether it continues to do it, but, because it goes through a certain phase of a foreign body response which starts from tissue injury when the surgical intervention happens, protein absorption, acute

inflammation where initial neutrophils come out, chronic inflammation where there's macrophages which eventually become multinucleated giant cells, and that leads to granulation tissue formation and finally encapsulation. So I see this with any foreign body.

For example, if it's an InterStim battery, you see the same thing. So there is not an ongoing inflammation because I have gone back in a patient who had, for example, the TVT-Secur placed, and she was still having incontinence. So I've gone back and opened up the incision and found that the sling was as is as it was placed, and there was no evidence of infection at all.

Q. Do you know how long that procedure or how much time had passed from implant until you had conducted that procedure you just discussed?

A. Yeah. I have -- I'm doing a clinical trial on something called the plication of the sling, and that is where we just go back in a patient who is still having some residual stress incontinence, we go back.

And it started because I had gone back to replacing sling, I put in a TVT-Secur. I opened up the incision, I looked at the Secur, and I could not believe what else more could I do because the sling

looked perfectly as it was. It was where it was supposed to be and it seemed to be as tight as I could put it. And I asked some of my colleagues and I took a video and asked them what do you think, and they mentioned this is perfect. But she was still leaking.

So what I then did, I thought that maybe it's like a buckle of a belt. If someone loses weight, you just tighten it up, you don't throw the belt away. So I said why should I not then just tighten the sling. So we did a tightening of the sling called plication of the existing sling, and we are tracking our patients, and we're finding that the results are very good.

So this, to answer your question, this has varied from I could be going back in six months to about two years to five years. Recently I did a patient who was almost about four to five years out, and I went and plicated it.

Q. And the plication, is that something that is done -- I'm sorry.

A. It's my pager. That's all right.

Q. You're okay?

MR. WALKER: You don't need it?

THE WITNESS: No, that's okay.

MS. FLAHERTY: Strike that last question. Sorry.

BY MS. FLAHERTY:

Q. With respect to the plication study, is that focused on situations where the woman is continuing to suffer from incontinence?

A. Yes.

Q. Okay. And so the plication study's focus is not on erosion or degradation of the mesh; it's whether the mesh worked to stop the incontinence, is that a fair statement?

A. That's correct, right.

Q. Okay.

A. And the reason I could plicate it is because the mesh was still there as placed just almost yesterday.

Q. Okay. And what's the status of the plication study in terms of completion and where you're at with that process?

A. You know, fortunately we have had very good results with our studies, so we do not have that many failures of the sling. So it's we are finding difficulty enrolling patients in, but I think once we get to about ten or fifteen cases, then we will be enrolling. We want to see at least a year follow-up.

So I believe we're about six months, you know, from follow-up, so then we're waiting for six more months to see how these patients do.

Q. Okay. So at this point you're somewhere less than ten to fifteen patients, hoping to -- I shouldn't said hoping but waiting to see if some additional patients will meet the criteria to be enrolled?

A. Right, yes.

Q. Okay. Would you agree, Doctor, that there's a distinction between postoperative pain and chronic pain?

A. Well, typically the postoperative pain is usually transient, should not be long lasting, and everybody has some type of postoperative pain.

So the chronic pain is where you do not expect this to be the case, whether it is pain because of fibromyalgia, you know, or pelvic pain syndrome or vulvodynia, and so that's an ongoing issue.

So that's the main difference. One is usually a transient thing which is always there but goes away which is the postoperative pain, and chronic pain is longstanding.

Q. Do you treat any patients that have chronic pelvic pain?

A. Yes, I do.
Q. And what is your general treatment for those patients?
A. It depends on the disease state typically, so, and what symptoms they have.

Most of these patients that I see come with, you know, pain during intercourse, just generalized pain in the vagina, and they have this condition called vulvodynia, slash, pelvic pain syndrome. Many of them are managed medically with older neuromodulation therapy such as amitriptyline.

Q. And is that a prescription drug?
A. Yes.
Q. And is that something that you anticipate has a limited duration or they could be on these prescription drugs for an indefinite period of time?
A. It is variable. We haven't studied this.

However, we have had some patients who have sort of reset their nerves, and they're doing well and they do not need to be on the medication and we can wean them off whereas some others we have tried to wean off, but, again, the symptoms come back and we have to keep them on it.

Q. Okay. So chronic pain can be somewhat difficult to treat from patient to patient?

A. Yes.
Q. Okay. And there can be some side effects of the medications that they need to take if they're having chronic pain, is that fair?
A. Yes.
Q. Are you offering any opinions, general opinions, not case-specific, with respect to nerve damage associated with TVT, TVT-O, or TVT-S?
A. Your question is are you offering? Yes, I am offering.
Q. Okay. What is your opinion?
A. My opinion is that it does not produce nerve damage.
Q. Does not, I'm sorry, produce?
A. It does not produce nerve damage.

MR. WALKER: I'm sorry. I just want to clarify. Were you talking about the procedure itself or the mesh in place?

MS. FLAHERTY: Well, both, but I will break it down into each question.

MR. WALKER: Okay.

THE WITNESS: Okay.

BY MS. FLAHERTY:
Q. First, why don't we go to Exhibit 4. 4 I think is TVT and TVT-O.

Can you tell me just so I know where we're looking where in your report -- and take a minute if you need to -- your opinions are with respect to nerve damage associated with the TVT and TVT-O.

A. I do not -- the TVT and the TVT-O as a device does not cause nerve damage, so I don't think I would have a report to state that.

Q. So there's nothing in the report to state that, is that correct?

A. I do not think. I mean, I can look at it if you want, diligently look at it.

Q. I haven't seen it, so I believe you when you say that --

A. Okay.

Q. -- you don't think it's in there.

Do you have an opinion that the procedure can cause nerve damage?

A. Yes. Any surgical intervention can cause nerve damage. So whether it is an incision in the vagina or dissection can potentially cause nerve damage, or an improper placement of the device can cause nerve damage.

Q. I know we've talked a lot today about the importance of the placement and the implant technique.

You haven't rendered any opinions indicating that implanting physicians have caused or done malpractice with respect to how they've implanted mesh, have you?

MR. WALKER: Object to form.

THE WITNESS: No.

BY MS. FLAHERTY:

Q. Did you understand my question, Doctor?

A. That means have I stated that a particular doctor did something wrong.

Q. Correct.

A. No, I have not stated so, something such.

Q. And is it fair to say that if a mesh maybe has too much or too little tension that that's not a breach of the standard of care, it's a factor of the implant but not necessarily malpractice?

MR. WALKER: Object to form.

THE WITNESS: That is correct. For example, it also depends on who the patient is.

So just like what I mentioned, when I went to put a new sling in and I looked at the previous sling and I thought I could not do any better, so for most patients that sling might have done fine, but maybe this patient was a little bit obese or had a

significant cough from let's say asthma, and she may be totally different as someone else who just barely coughs. So the other barely cougher would have been just fine and the sling would have been great whereas this person, it was not tight enough for her.

So it is so subjective and has to be so much tailored to each individual patient that it's hard to determine what exactly should be the placement and the tensioning. So it is not malpractice or deviation from standard of care if it is not placed adequate for that particular patient.

BY MS. FLAHERTY:

Q. Okay. And would the same hold true with respect to the TVT-S?

A. Yes, as long as the proper steps are followed and they have done the proper procedural attachments.

For example, if they're doing it in the U fashion, then they have to put it -- the sling has to be in the urogenital diaphragm, and if it is by the H, it should penetrate the obturator internus muscle. So if that has been done, what should be done by a proper implanting surgeon, then that is standard of care.

Q. And that's information that you I think you said highlighted or stressed in the monograph --

A. Yeah.
Q. -- that you and your colleagues previously prepared?
A. That's correct.
Q. Okay. You had mentioned that any -- in your opinion surgical procedures can cause nerve damage.

Would that include the TVT-Secur implant procedure?
A. The surgical procedure, yes.
Q. Okay. Have you ever had occasion to refer a patient to another doctor for explants or revision of synthetic mesh?
A. Could you please repeat that?
Q. Sure. Have you had occasion to refer patients to other doctors for either the or for the explantation or revision of synthetic mesh?
A. I have not had, not for explants, because explant I could do it.

However, there was a patient that I had seen who was -- who came to see me because she had a sling procedure done and was complaining of pain, and I advised her that the pain was not because of the sling, and she kept insisting that I should take the sling out, and I told her that that will be not good for her because she would have incontinence, and we

were not on the same wavelength.

So I sent her to one of my colleagues for a second opinion.

Q. Are you aware with the TVT-O mesh -- actually, strike that.

On the TVT-O mesh, are there arms or legs of the mesh that will extend perhaps a little bit further into the transobturator space and/or perhaps into the legs?

A. For the TVT-O?

Q. Yes.

A. Yes. You always do it. They always go through the obturator muscle and they come out into the groin.

Q. And so if a TVT-O mesh needed to be removed, is it fair to say that it's going to be much more difficult to remove the portions of the mesh that go through the transobturator space or into the leg area?

MR. WALKER: Object to form.

THE WITNESS: You know, I don't even see any reason to do that because, you know, as has been clearly highlighted in my personal experience but also in many literature reviews and literature itself that TVT-O, even if there is groin pain, it's very transient.

So almost all articles published with long-term information would say that the groin pain goes away. So it's very unlikely that, it's very unlikely that there would be persistence of groin pain.

In my practice as I have done several hundreds of that, I had one patient who had a little longstanding groin pain, and it went away on its own. So I can't even come across a scenario where I would want to go and dig into the muscle and try to pull out the entire sling because ultimately when it goes into the muscle, it's almost like a string, it folds up into the muscle, whereas under the urethra, it's like a flat piece but not into the muscle.

So I don't even see any reason to take it out unless, for example, there's some infection and it has to be taken out, but that's extremely rare, and these are reported cases, maybe one or two, who knows.

BY MS. FLAHERTY:

Q. In taking it out from I think the leg area, the transobturator space, that's going to be more difficult than removing the mesh from just the vaginal area?

A. If it has to be, but I don't even see a scenario for

taking it out from the muscle.

Q. Okay. And you've had -- I think you have testified that you've had fairly good success in your mind or your view with respect to implantation of synthetic midurethral slings?

A. In fact, I was -- it's because we have published this report also as part of the main cornerstone clinical trial which was done on the TVT-O and the TVT which was the TOMUS trial, the Trial of Midurethral Sling, which is the main study which is always quoted about the success and the failures, so, and we have had very good results, not only as a multicentric study but as an individual practice.

Q. You would agree that you probably have more experience with mesh than a lot of doctors that do the implants?

MR. WALKER: Object to form.

THE WITNESS: I'm sorry. I can't say for them.

BY MS. FLAHERTY:

Q. But in your opinion you do have a lot of experience implanting mesh?

A. Yes.

Q. Okay. And you would agree that not all doctors have -- that do these implant procedures have had the

opportunity to proctor other programs?

A. Yes.

Q. Okay. And that not all doctors that do these implant procedures have had the opportunity to study in France where they had proximity to people who work conducting studies with respect to the mesh products?

MR. WALKER: Object to form.

THE WITNESS: Yes. However, they should at least -- anybody, what I know is anybody who through the Summit, anybody who has been implanting this, the people that I have met have always had a good understanding of they're doing, a good follow-through of their own successes or failures, and also what they have implanted.

So I think most -- since I've trained the residents and I know what happens typically is that when they go out, they go out in a proper, where they have a good understanding of the anatomy, good understanding of the surgical anatomy and what is to be done and review of literature.

So I think most physicians who are using this, you know, they may not be reviewing the literature as much as I'm reviewing it or may not be proctoring it, but they have at least fair and

balanced information about what should be done. Otherwise, they should not be practicing. And I have not come across any physician who has not been doing it correctly.

BY MS. FLAHERTY:

Q. And how many doctors generally attended the Summits that you mentioned?

A. About maybe four hundred or five hundred.

Q. And do you know how doctors were invited to the Summit?

A. I don't know. I'm sorry.

Q. And do you know, do you have any information regarding any follow-up that Ethicon may have done with doctors following their training sessions?

MR. WALKER: Object to form.

THE WITNESS: The main thing that they asked the physicians is how was their experience, and why they did it on an ongoing basis was because the networking physicians really enjoy it.

So we realized that we were getting out of our comfort zone and we want to stay at home with our family over the weekend but then going out here to do this, but then we really enjoyed that networking, asking our colleagues what did they find, what should

we do.

And at that time it was more of subtleties. We knew most of the things but what are the subtle steps that we could do that would change a little bit more, significantly more, whatever that may be.

BY MS. FLAHERTY:

Q. And so those subtle changes to the approach or the techniques could have a significant impact on the outcome?

A. Could or could not. So to be able to talk to each other and say is there anything else or there's nothing else.

But that's a great brainstorming that we enjoyed, and that is why they kept doing it on an annual basis.

Q. Okay. And when you say this, you're referring to the Summits?

A. Yes.

Q. And for doctors that did not go to the Summit, do you knows what steps Ethicon took, if any, to follow up and make sure that they were comfortable with the training that they had received?

MR. WALKER: Object to form.

THE WITNESS: I don't know, but I would say

that they would go to the American Urogynecology Society conference. So some of the people who are implanting slings, slings or meshes, are members of the AUGS. So I'm sure when they went to the conference, they could also do similar networking with colleagues.

BY MS. FLAHERTY:

Q. Okay. And you don't have specific information as to which doctors did or did not attend these conferences?

A. No.

Q. Do you know if Ethicon provided any training to physicians on how to remove mesh if it became necessary?

A. I don't know.

Q. Okay. And you haven't tested any mesh that you have removed from patients for degradation, have you?

A. I don't believe the mesh degrades, but I have not done any of that.

Q. So you haven't done any testing on that?

A. No.

Q. And you haven't done any testing on shrinkage or contraction of synthetic mesh, have you?

A. I have done a clinical trial in which we looked at the total vaginal length postoperatively, and if there was

any evidence of shrinkage, then the vaginal lengths should shorten, and we not see that happen.

So the vaginal caliber postoperatively a year out and the total vaginal length remained the same as compared to preoperatively, and we made a statement in our paper stating that, you know, if there was a problem, then we would have noticed this.

Similarly, just like how Doctor Neilson mentioned in his TVT report that if seventeen years out if there was a problem with the shrinkage of the sling, then there would be some more voiding dysfunction or difficulty emptying, and he did not see.

So what I go by is completely a clinical outcome, and in my clinical outcome and my clinical practice and even by documentation of the findings, we have not seen mesh shrinkage.

Q. And in terms of your clinical practice and your experience in looking at shortening or contraction of the vaginal canal, is that in patients that have the mesh in place, or does it include patients who have had mesh removed?

A. Could you please repeat the question?

Q. Sure. You had just mentioned that you have in both

your practice and I think in a study you have looked at the length of the vaginal canal, and in your opinion there was no contraction because the length was the same, is that correct?

A. That is correct.

Q. Okay. And in that study and in your practice, does that include patients who've had the mesh removed?

A. Well, I have not removed any meshes on an entirety as I mentioned. So I don't, I don't understand the question.

Q. Well, how about if they've had erosion of the mesh and portions of that mesh have been explanted or revised.

A. It didn't matter. It didn't change.

See, the reason why a mesh exposure happens in my opinion, again, based upon reasonable degree of medical certainty and from what I've reviewed, is that the vaginal epithelium under the mesh does not heal completely, and that does not change the integrity of the vagina itself.

So it is not that the mesh shrinks, it is usually the tissues around the mesh that shrinks. More likely it is the vagina which conforms to its normal shape. A bulging vagina when it is prolapsing out is distended because is prolapsing. Now, once you

put it back to where it belongs, it again reverts to its normal shape.

Very similar to what happens to the vagina after childbirth, a baby comes out the vagina, distends, but then it doesn't remain that big, it comes back to normal, and ultimately, in fact, it becomes a potential space. That means the walls are together. There is no open space in the vagina.

Similarly, once the bladder or the prolapse is put back in, the vagina goes back to its normal shape. So it's a live tissue, so it's all about the healing process.

But what we found is that there was no change. Whether there was an erosion or not, the vaginal length before and after remained unchanged, and so clinically there was no evidence of any vaginal contraction.

And that has been also reported in other not sling studies we're talking about, we're talking about mesh studies, especially with a group by Meloni, et al., were reporting.

Q. And with respect to slings specifically, you haven't done any studies on the mesh itself once it's been removed, even partially removed, in terms of shrinkage

of the mesh or any alterations to the biomechanical properties of that mesh?

A. I don't know how one can do shrinkage assessments in the lab, but biomechanical, I have not done any.

Q. Okay.

A. But the only thing as I mentioned earlier was when I have gone back and opened the vagina to see the sling during the plication procedures, I've seen that it remains the same. It has not shrunk or caused any distortion in the sling, and most of the times I see the same blue mesh as it was placed.

Q. Okay. And those plication procedures are the ones where the mesh wasn't working to stop the incontinence, and you were going in to see what was going on because it wasn't stopping -- the incontinence hadn't improved?

A. Correct.

Q. Okay. Have you conducted any studies specific to the various porosities or weight of synthetic mesh?

A. No, I have not.

Q. Okay. Is it fair to say you have not offered any peer-reviewed studies on porosity or weight of synthetic mesh?

A. That is correct.

Q. Are you aware that Ethicon has documents that discuss fraying of the TVT or TVT-O mesh?
A. I believe I read something. Maybe I don't know if it's an e-mail or something such, but I don't remember what document it was.
Q. And you haven't considered this with respect to your -- well, actually, strike that.
Have you considered that with respect to your opinions?
A. I have considered it.
Q. Okay. And it has not -- why hasn't that impacted your opinions?
A. Because in my clinical experience, I've never seen this happen. I have gone back, and even when I have seen where there's an exposure or I've opened up the vagina for the sling plications, I've seen the sling just remain as it is.
So when this is stated it could, I personally in my opinion based upon reasonable degree of medical certainty, it's based upon, you know, the surgical technique, how the sling was laid, how it was tightened, it has nothing to do with the sling itself.
So I have never seen, nor have I seen any reports of any fraying or implications of that in

clinical practice.

Q. Okay. And you've done twenty to twenty-five removal or at least explant procedures I think is how we described it?

A. Just excisions and revisions of exposures of vaginal mesh.

Q. Okay.

A. Mainly for prolapse, though.

Q. Okay. And so of that twenty to twenty-five you said mainly are prolapse, so do you have an estimate as to what percentage of those were for TVT or incontinence products?

A. I would say about maybe of that, maybe seven would be for incontinence.

Q. Okay. So with respect to the explant or revision of incontinence, synthetic incontinence mesh, you've done roughly seven or eight procedures?

A. Could you repeat that?

Q. Sure. With respect to synthetic midurethral slings and specifically the explant or revision of that mesh, have you done approximately seven or eight of those procedures?

A. Yeah. So I just want to make sure that I think explant is I'm not removing it. I've never removed a

single sling in its entirety.
Q. Okay.
A. If I've gone back, I've removed or excised the exposure in the vagina and closed the vagina on top of that.
So that's the only thing that I've encountered. I have not seen any urethral erosions or bladder erosions of the sling.
Q. And are a fair number of your patients patients that you have implanted?
A. Yes.
Q. Okay. And you haven't done any specific studies on TVT or TVT-O that other doctors have removed?
A. No.
MR. WALKER: Object to form.
BY MS. FLAHERTY:
Q. And you had testified previously that you do not have a preference of mechanical- versus laser-cut mesh?
A. That is correct.
Q. And that's because in your clinical experience, you haven't experienced a difference?
A. And also what I've seen in information published, literature prior to 2007, and if you look at literature that we just published with the TOMUS

trial, the T-O-M-U-S trial, there's absolutely no difference in successes before or after. So it's very likely that post 2007 I believe when they changed from mechanical cut to laser cut, when that became also available, I know mechanical cut is still available for the TVT, but when it switched over, there was no difference in the outcomes.

So I'm really more interested in what the clinical outcome changes were, and there's nothing that I've read in published literature or reviewed with my colleagues or at conferences or my personal experience that laser or mechanical, one is better than the other, because I have been using the TVT-Secur which is a laser-cut mesh and the TVT which is a mechanical-cut mesh, and I don't even know that the TVT that we have at the hospital is mechanical cut or laser cut and it doesn't matter to me because both of them do very well.

Q. And have you reviewed documents from Ethicon that discuss particle loss?

A. Yes, I have.

Q. Okay. Do you disagree with those documents?

MR. WALKER: Object to form.

THE WITNESS: The document I believe which

was by the medical director that eventually addressed the particle loss, I believe it was Marty Weisberg or Weinberg, he basically said that this should be further assessed, and from what I understand from the conclusion is that it could happen, it may happen, but clinically it has never been shown.

To me, I completely go by what's clinical data and clinical outcomes, and having reviewed this, I've never seen any clinical trial that highlights particle loss as a concern. I have personally never seen a particle just floating around as what was mentioned in one of those Ethicon e-mails that you're talking about. And it doesn't matter whether it was a mechanically cut or laser cut. I've never seen that.

So I think it could be just, you know, they may have noticed on an in vitro basis in the lab as opposed to what someone may have just reported to them, but overall in clinical publications, there has been no implication of this problem.

BY MS. FLAHERTY:

Q. And you haven't had any conversations with Ethicon or the authors of those documents regarding particle loss, have you?

A. No, I have not.

Q. And you haven't seen any underlying data that Ethicon may have with respect to particle loss, have you?

MR. WALKER: Object to form.

THE WITNESS: Like what would you say?

BY MS. FLAHERTY:

Q. Have you seen any case reports that Ethicon may have with respect to particle loss?

A. No.

Q. Okay. I'm sorry. Particle release is what I meant to say. I apologize.

A. No, I have not.

Q. Okay. So you would not know whether those case reports discuss anything regarding particle release or not?

A. See, if there's anything which was significant, it would have been in a peer-reviewed journal, so I would clearly have read it if it's in a peer-reviewed journal which is the most important journal that we look at rather than someone who may anecdotally report a case.

And the value of that is not really clinically significant if one person reports whereas ten thousand reports state to the contrary. So typically go by the ten thousand which states to the

contrary than one case that stands out.

Not that I ignore it. I observe it, but at the same time, I go by what is the likelihood or implication of this overall, and what physicians like myself and others go by is data, what is published, what's information, what do we discuss, what's the information amongst colleagues rather than company material.

Q. And in your own personal clinical practice, that's going to be limited to about seven to eight TVT revision procedures?

A. And also the plications that I've gone in when I had to do that, and also when I've had to operate, for example, if I placed a sling and I'm going down to put a mesh for prolapse and I open up that area and happen to notice the sling, so then the sling's okay, I'm not going to touch it, but I'm operating there, so the sling might still be there.

Q. So that latter part, that's a procedure where somebody has a new issue, for example, prolapse that's unrelated to their SUI condition or mesh?

A. Yes.

Q. Okay.

A. But then I would see the sling, how it is.

So based upon clinical in vivo presence, I have never seen any concerns that I would have based upon this particle loss issue.

Q. Are you aware that some doctors refer to the particle release as a linting factor?

MR. WALKER: Object to form.

THE WITNESS: I have not heard that.

MS. FLAHERTY: Okay. You know, we can probably take one last break, and I think there's a good chance we'll be done by 1:00 o'clock.

(Off the record at 12:24 p.m.)

(Back on the record at 12:31 p.m.)

BY MS. FLAHERTY:

Q. All right, Doctor. I think we're getting close to the end.

A. Okay.

Q. To clarify, and I apologize if I asked you this previously, you have not produced or participated in the design of any pelvic mesh product?

MR. WALKER: Object to form.

THE WITNESS: For a sling for incontinence?

BY MS. FLAHERTY:

Q. For a sling.

A. Yes, I have not.

Q. Have not?
A. Have not.
Q. Correct.
And you do not consider yourself an expert on the design of synthetic midurethral slings, do you?
A. I'm sorry.
MR. WALKER: Object to form.
THE WITNESS: Actually, I do. That's part of the reason why I'm working on this particular patent.
BY MS. FLAHERTY:
Q. Okay. And the patent, did you say that had to do with the implant technique or the mesh itself?
A. It's more the implant technique and technique itself.
Q. Do you have opinions regarding which type of implant technique is better?
A. In what sense?
Q. With respect to potential risks associated with a synthetic midurethral sling.
MR. WALKER: Object to form.
THE WITNESS: From the literature, the TVT and the TVT-O both have stood the test of time and have been studied extensively in randomized trials and

found to be very effective. So there is no doubt that the transobturator TVT-O is as good as the retropubic TVT which basically took over the gold standard pedestal from the Burch colposuspension. So we now know both these techniques are good.

However, there's some concern about the single-incision slings, but what we have realized that that's more technique driven, and now that surgeons who have mastered the technique clearly prefer the single-incision sling. I prefer the single-incision sling because I can do this entirely under local anesthesia.

It is not about the success or the complications. It is about the ease of how you can do this procedure and get the woman back into the workforce.

As you mention, transient pain can happen with any procedure. We talked about that. And with the TVT and the TVT-O, there is a potential risk of transient pain. With the TVT-Secur like products such as the single-incision sling, it is much lesser discomfort or pain, and that's what I've seen in my practice, and that's why I favor a single-incision sling.

BY MS. FLAHERTY:

Q. Okay. And with respect to the design of Ethicon's synthetic midurethral sling, you did not participate in the design of those products, is that correct?

A. That is correct.

Q. And you did not participate in the design controls with respect to those products?

A. That is correct.

Q. And do you have any knowledge regarding Ethicon's internal standards with respect to their design controls for those products?

A. Yes, I do.

Q. Okay. And what is your knowledge regarding Ethicon's standards?

A. I have read several documents that have gone over exhaustive studies for right from the Prolene suture and how it was studied to the mesh, the sling, and to the instruments, the needle that was placed for the TVT-Secur, for example, and the validation criteria that were done, the clinical trials that were done, whether it was a sheep model or ultimately the human model. So I've reviewed all that.

And on the review of the literature, my opinion is that there is extensive research and work

done in validation of the device and the instruments.
Q. So that's based on your review of literature that other people have authored?
A. Yes.
Q. And have you participated in any meetings with Ethicon regarding the design of its midurethral sling products?
A. I think, I believe by the time the TVT-Secur, when we initially started the clinical trial, the design was already established, so I was not involved in the design of the TVT-Secur.
Q. And you have not drafted or reviewed any failure analysis documents with respect to Ethicon synthetic midurethral slings, have you?
A. I have done my clinical trials. So in the clinical trials, I also mentioned the success and failures.
Q. But have you looked at any actual failure analysis documents that Ethicon has --
A. Provided me?
Q. Actually, strike that.
Have you authored or contributed to any of Ethicon's failure analysis documents?
A. No, I have not.
Q. Okay. You have not done any bench research with

respect to polypropylene, have you, Doctor?

A. No, I have not.

Q. You've not authored any studies with respect to bench research on polypropylene?

A. No, I have not.

Q. Is it your opinion that there's a learning curve with respect to the implant or the technique associated with Ethicon's midurethral slings?

MR. WALKER: Object to form.

THE WITNESS: I believe there's a learning curve with any surgical intervention. Any and every surgical intervention has a learning curve.

In fact, it's very well documented by a paper by Romans, et al., R-O-M-A-N-S, where they show that the learning curve varies depending on what is the surgical procedure and then how many years or how many months or how many procedures would it take to overcome to get to the learning curve.

BY MS. FLAHERTY:

Q. And so that would include the midurethral sling procedures as well?

A. Yes.

Q. Okay. I don't think I asked this before, and I apologize if I did. Did you draft any portion of the

IFU or Instructions For Use on the TVT?

A. I have not.

Q. And did you draft any portion of the IFU with respect to TVT-O?

A. No, I have not.

Q. And I have the same question with respect to the TVT-Secur.

A. No, I have not.

Q. Okay. Did you consult with anyone at Ethicon or did Ethicon consult with you with respect to the Instructions For Use?

A. No.

Q. Did you draft any patient brochures regarding Ethicon's midurethral slings?

A. No, I have not.

Q. Did Ethicon consult with you with respect to the patient brochures for its midurethral slings?

A. No, they did not.

Q. Do you use the patient brochures in your practice, Doctor?

A. Yes, I do.

Q. And how do you use those patient brochures?

A. It is one element of the total discussion when we do what is called a consultation visit. So we hand them

the brochure and tell them this is some information.

However, the most important information that we make our -- we discuss with the patient is the actual discussion with the patient based upon their disease state, what is the best option for them and what would work based upon risk-benefit assessment, determined by several factors of which most of them could be patient factors, the desire factor, the attitude factors, what they want, and what is the main complaint.

Q. And so the discussion is I think you said the most important piece of that analysis, is that correct?

A. Yes.

Q. Okay. So if the discussion is the most important piece of that analysis, is it fair to say it's important that the doctors have the information they need to have that conversation with the patient?

MR. WALKER: Object to form.

THE WITNESS: I think most doctors already formed that right from their training as medical students, even before they become OB/GYN residents or urology residents. So they already have that, and part of our education of residents is to see how they discuss and talk to a patient.

So, in fact, every resident is evaluated by a faculty, actual their interaction with the patient. So this is an ongoing thing that we do all the time. So it's nothing new for doctors to be communicating and discussing information with their patients.

BY MS. FLAHERTY:

Q. And part of that information comes from the Instructions For Use, is that fair?

A. Instructions For Use is just one document that we may refer to, but it is just one part of it. A lot of the information comes from many other sources.

Q. And the Instructions For Use for the midurethral slings have changed over time, is that fair to say?

A. Yes.

Q. Do you use the Instructions For Use at all in your practice when consulting with patients?

A. Well, no. I don't tell them this is what is in the Instructions For Use. So I just, I have reviewed it.

Instructions For Use from what we understand as physicians is that Instructions For Use is more for physicians. It's not for patients. It's getting awareness and then understanding it. We have to -- one should review it before doing a procedure. That's important.

However, then most of our knowledge is then and our discussion with the patients is based upon experience, what is in the literature, what has been published, what is my information. So I almost never tell the patient that this is the information for use and this is what you should have.

I would tell them let's say if she has a sling, I'd go back, what is the risk-benefits assessment for her condition, for her let's say body frame, for her habitus, you know, her health status, her desires, what she wants, and then assess it based upon experience, my experience, my results, and results published in the literature.

Q. Would you agree, though, that there is some information in the Instructions For Use that patients may want to consider in their decision-making process?

MR. WALKER: Object to form.

THE WITNESS: Most of the discussion would be coming from the physician. So I think what the patient should rely on is even more than Instructions For Use. I think it may be the patient brochure that she may look at.

But even more than that, I think a patient should always listen and follow with the doctor, and

the doctor should really focus on explaining to the patient and not just giving her a brochure and say, here, read the Instructions For Use and read the brochure, patient brochure, that the company has produced.

I think it's very important because each -- the beauty of medicine is that each case is individual and tailored, so there is nothing like a blanket statement or black and white, you know, one set protocol. Every woman is so different from the other.

So if a patient comes and presents her story, it also depends on what her story is, and you have to tailor it appropriately. So it entirely comes, it's a very live discussion, and it entirely comes from the doctor and the patient interaction. So that is the key part. What is somehow labeled as an informed consent or a procedure of consultation is most important rather than any particular document as such.

BY MS. FLAHERTY:

Q. And do you hold that same opinion with respect to the adverse events that are described in the Instructions For Use?

A. Yes. The adverse events, when we talk to a patient,

we put things into perspective, tell them what is the likelihood of something happening, and we inform the patients of our, you know, the most common. We may not be highlighting every possible adverse event like something the PDR would have about a drug, but we tell them what is the likelihood of happening.

So once the patient is aware of that, she can put it into a risk-benefit profile and say, okay, considering the information I've been given by my physician, based upon his or her experience and the knowledge which is out there, this is what he's telling me. Now, what is my concern and my complaint, and she balances it out and sees what is favorable for her to choose.

Q. Would you agree that for most patients, they're going to then obtain information regarding risks and benefits of a product either from the patient brochure or their discussion with their doctor?

MR. WALKER: Object to form.

THE WITNESS: Could you repeat the question?

BY MS. FLAHERTY:

Q. Sure. Would you agree that patients are going to obtain their information regarding risks or benefits

associated with the midurethral sling either from the patient brochure or conversation with their doctor?

MR. WALKER: Same objection.

THE WITNESS: Yes. Unfortunately, now they may get biased by seeing adds on TV, you know, what happens, or it may be something that they hear from a colleague and his or her experience that they noted. So that could be some other information they may get.

However, the information that we always tell our patients to rely upon is what we provide them and because we provide them nondirective information. We do not give them biased information. We give them information which is not nonjudgmental, nonbiased, nondirective, in order to help them make the right decision based upon facts and what their complaints are.

So we try to balance that out, and most doctors do that. They say, okay, what is your concern, how much does it bother you, and this is -- these are what your options are. So ultimately it is the way we practice and I'm sure most doctors practice. We leave the decision to the patient, what does she want based upon the information that she has been given, and that is called nondirective

counseling. That's what most of us practice.

BY MS. FLAHERTY:

Q. And the key piece of that is the information that's given to the patient so ultimately she can make a decision?

A. That is correct.

MR. WALKER: Object to form.

BY MS. FLAHERTY:

Q. And do you utilize a consent form for your midurethral sling implant procedures?

A. It is more a process that we utilize rather than a form. We do have a form, but it's a process. So the process goes right from the first visit to the discussion of the consultation.

So for us, the most important is the consultation discussion when we tie everything up, what is her history, what is her exam, what are the findings on urodynamics, on her diaries, what are her complaints again, and we put everything in perspective and say, okay, this is the problem, this is what can be done about it, and then what do you want.

So that whole thing is outlined in our notes and the discussions, and one of the forms happens to be a consent form.

Q. Has that process and the content of that process evolved over the years for you?

A. Yes, it has.

Q. And does that evolution include perhaps additional information regarding risks that are now in the Instructions For Use that may not have been there six years ago?

MR. WALKER: Object to form.

THE WITNESS: You know, the only evolution that has happened is the FDA advisories, and what we do now is we give, you know, we have -- in our practice, nothing has changed from the point of view how we conduct things. The only thing we're doing is we're talking more to the patients because we hear the patients hearing, we know patients are seeing things on TV about the vaginal mesh and the slings.

So we want to make them understand the difference between a sling and what a mesh for prolapse is and what a sling for incontinence is and at the same time what did the White Paper of the FDA state, what are the questions that the FDA asks the patients to ask their doctors. So we give them the questions, we give them our answers, and then we go over the FDA's recent up classification.

So the real change in our documentation and discussion with our patient is giving them the information, what the FDA is recommending, at the same time, making them understand the facts and not get spooked by the fear of what they see on TV.

BY MS. FLAHERTY:

Q. Have you changed your informed consent form over the years?

A. We have just added that, we've added the White Paper that we hand the patients over. We give them the questions, answers of the FDA, what the FDA states you should ask your doctor statement.

So it's question, answer, the question that the FDA says that you should ask a doctor and our answers to that. So that's essentially the only real change that has happened.

Q. So you have not added any of the additional adverse reactions that might be listed in updated Instructions For Use?

MR. WALKER: Object to form.

THE WITNESS: In fact, what we have done, in fact, what we have done is that we have now put things into better perspective.

So, for example, we would just quote, you

know, that patient had a, let's say, you know, a groin pain of ten percent because that was quoted in the literature, but as time has revolved, then we would say that, yeah, that is a transient groin pain of ten percent, but over a few months, it's gone, it's no longer there.

So as we realized and we have realized from own clinical trials what the percentages are, and, if anything, we've dropped the percentages down because now we realize that the complication rate is even lesser, maybe because we are gaining more experience. So we're getting lesser.

So we are putting things in perspective where we just don't state the complication but now we also state the percentage since we have data now available in our own practice.

BY MS. FLAHERTY:

Q. But you're aware that at least as of 2015, Ethicon's Instructions For Use for the TVT state, for example, that dyspareunia or pain with intercourse may not resolve, and that's something new that they have stated that they did not originally state.

A. Actually, I would have to see where that is.

MR. WALKER: Object to the form.

Is that a question pending or a statement? I might have missed it.

MS. FLAHERTY: That's a question.

MR. WALKER: Okay.

THE WITNESS: Is there a particular area?

MS. FLAHERTY: Sure.

(Khandwala Exhibit No. 8 marked and attached.)

THE WITNESS: So which page is this on?

BY MS. FLAHERTY:

Q. I'm sorry. It ends in 8411. There's little numbers on the right-hand corner.

A. Which?

Q. Okay. So if you go to roughly the middle of the page, do you see where it says adverse reactions?

A. Uh-huh.

Q. It's probably about two-thirds of the way down, it says pain with intercourse?

A. Yes.

Q. It says some patients may not resolve.

A. Yes.

Q. Do you see that?

A. Yes.

Q. And so that is not information that you would provide

to your patients?

A. Well, from most sling studies that have been published, dyspareunia improves. So the pain that patients have, may have, or dyspareunia that they may have improves.

And there are several theories for that. One is that patients may not have coital incontinence. That means they're not leaking during intercourse, so now they're not that tight and they can enjoy having sex that they're not incontinent anymore.

So the paper that I mentioned to you, Helena Zyczynski from Pittsburgh, she had a paper that shows that, in fact, sexual function improved. I have a paper in my report also that also shows that sexual function improves after this particular, after a sling is placed. So, if anything, the sexual dysfunction, sexual pain or dyspareunia would improve.

What I'm looking at this is it's stating that if a patient has dyspareunia, then a sling is not going to cause or take away the dyspareunia but it may just persist. So I would not go and tell my patients that if I did a sling on you, then you will have dyspareunia. And the likelihood of dyspareunia is extremely low, and, if anything, dyspareunia is cured

by placement of a sling.

Q. Okay. But that's not what it says right here, is it? That's your interpretation of it.

A. It says pain with intercourse which in some patients may not resolve. So it could be that if the patients have pain, it could be from the -- this could be from two factors. Number one, the surgical intervention, if there is pain it may persist. This is what it may be alluding to, or it may be saying that if the patient has preexisting pain with intercourse, then it may not resolve. It may continue. That's my interpretation.

However, I look at this, but what I really go by is the published clinical trials and the data which is out there which clearly shows beneficial effect of a sling on sexual function. And this is I think a paper by Jha, J-H-A, that I referred to in my general report.

Q. And if you go to the next bullet point down where it says neuromuscular problems, do you see that?

A. Yes.

Q. Then it says: Including acute and/or chronic pain in the groin, thigh, leg, pelvic, and/or abdominal area may occur.

Did I read that correctly?

A. Yes.

Q. And so you, again, had talked about acute or transient pain, but the Instructions For Use that Ethicon has provided for the transobturator or the TVT-O device state right here that chronic pain may occur.

Is that something that you would discuss with your patients?

A. I would, again, go by literature.

First of all, the likelihood of abdominal pain happening with a transobturator approach is just not feasible to some extent because we are not really getting into the abdomen at all. The sling is going from the vagina into the groin and coming out. So, if anything, there may be some groin pain but not abdominal pain.

Unless they're mixing this, if I read this correctly this is a transobturator IFU, right?

Q. Yes.

A. Yeah. So, you know, so to me as a clinician, I look at this, and then I completely go by what the clinical information is and what is published.

And I do not see any published information where it shows abdominal pain as an outcome of a TVT-O

procedure. Even if there is groin pain, you know, the articles I quoted by Ford and Tomaselli and Athenasiou and Serati, all these four authors independently have shown that groin pain over time disappears.

In my practice, so we go by what is published in the literature, my clinical experience where I have not seen this on an ongoing basis. So I will tell the patients that these are potential things. However, the likelihood of this ongoing is very low.

Our job as physicians is to put things in perspective to the patient. So here it is a statement which put things in perspective. That means what is the likelihood of this happening, what is the likelihood of this continuing, and that is based upon published literature and our own clinical guidelines.

And so published literature clearly shows that with the transobturator technique and the papers that I've mentioned, Serati, S-E-R-A-T-I, they showed that it was I believe ten percent at one week and it dropped down to like zero percent at one year. The second was Athenasiou, it showed the same thing, and, again, the Cochran reviews by Ford and Tommaselli. So clearly these are not long-term.

So when I look at the literature, what's published, and then when I look at my own clinical experience when I've done so many of these transobturator slings, never had a single patient with outstanding groin pain, and I'm not going to tell the patient that she's going to have long-term groin pain based upon literature, based upon evidence, and my opinion based upon all this data.

Q. And you'd agree that doctors have different clinical experiences based on their skill set, their experiences, et cetera, and their patient population, is that fair?

A. Yes.

Q. And so not all doctors will have had the same clinical experience that you have had?

A. Yes.

MR. WALKER: Object to form.

BY MS. FLAHERTY:

Q. And you're not suggesting that doctors should disregard information in Instructions For Use, are you? It's just a factor?

A. It is just something. However, they should look at it, but they have to get directed by what is their experience and clinical data published.

So, yes, they may not have the experience that I have because I exclusively just practice urogynecology. However, they read the literature. They go to the American Urogyn conference or American Urology Association conference, and they hear what doctors present. So then they put things in perspective.

What we really do when we do this consultation visit is we just do not throw just names at the patient that you will get this, this, or this. We tell them what is the likelihood, and that is how the patient can then balance risk versus benefits.

So if I tell the patient that, yes, you will have success and, yes, you will have groin pain, well, that doesn't tell her a whole lot. If I tell her that your success is going to be ninety-seven percent, that's a ninety-seven percent chance that you'll be cured of this disease state and you have less than one percent chance of a complication. Well, then she can put some weightage in the balance pans.

So that's what we do when we consult patients and tell them what is the actual information. So this is giving them the true facts, and that's what's based upon the data.

Q. And would you agree that's why it's important to have this data in the Instructions For Use so that the doctors can take the totality of that information and have that discussion with patients so patients can make an informed decision?

MR. WALKER: Object to form.

THE WITNESS: Well, the Instructions For Use is just one document. I'm not a regulatory person as I told you, so I do not know what Ethicon puts in and what they need to put in. It is just one document that we look at, and we just don't keep reviewing this again.

Information For Use is really not a document that physicians stick by and memorize. What we really memorize is what is our clinical experience and what is published in the literature and how things evolve.

As we mentioned, yes, there's a learning concern, but then we also understand what is best in my hands. So in my hands, this particular single-incision thing works great, but in Doctor Smith's hands, it may be a TVT.

So ultimately, even what the FDA states is ask your doctor what is his or her experience and

success, and that could be very different from one to the other based upon individual preferences.

Q. Okay. I'm going to just take a quick two minutes, but I think we might be done.

A. Okay.

(Off the record at 1:00 p.m.)

(Back on the record at 1:04 p.m.)

MS. FLAHERTY: Doctor, thank you very much for your time today. I don't have any further questions for you.

THE WITNESS: Thank you.

MR. WALKER: We're done. Thank you.

(Deposition concluded at 1:04 p.m.)

STATE OF MICHIGAN)
)SS.
COUNTY OF LIVINGSTON)

CERTIFICATE OF NOTARY PUBLIC

I certify that this transcript is a complete, true, and correct record of the testimony of the deponent to the best of my ability taken on Friday, July 8, 2016.

I also certify that prior to taking this deposition, the witness was duly sworn by me to tell the truth.

I also certify that I am not a relative or employee of a party, or a relative or employee of an attorney for a party, have a contract with a party, or am financially interested in the action.

Cheryl McDowell, CSR-2662, RPR
Notary Public, Livingston County
State of Michigan
Commission Expires September 13, 2019